

Community-Based Development-  
Scaling up the correct use of misoprostol at home births in Afghanistan

by  
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## ABSTRACT

Globally, more than 350 000 women die annually from complications during pregnancy and childbirth (UNFPA, 2011). Nearly 99% of these, according to World Health Organization (WHO) trends (2010) occur in the developing world outside of a hospital setting with limited resources including emergency care (WHO, 2012; UNFPA, 2011). The most prevalent cause of death is postpartum hemorrhage (PPH), accounting for 25% of deaths according to WHO statistics (2012). Conditions in Afghanistan are reflective of the scope and magnitude of the problem. In Afghanistan, maternal mortality is thought to be among the highest in the world. The Afghan Mortality Survey (AMS) data implies that one Afghan woman dies about every 2 hours from pregnancy-related causes (AMS, 2010). Lack of empowerment, education and access to health care resources increase a woman's risk of dying during pregnancy (AMS, 2010). This project aims to investigate the prospects of scaling-up the correct use of misoprostol, a prostaglandin E1 analogue, to treat PPH in developing countries where skilled assistance and resources are scant. As there has been little published on the lessons learned from programs already in place, this study is experience-driven, based on the knowledge of industry experts. This study employs a concurrent triangulation approach to synthesize quantitative data obtained from previous studies with qualitative information gathered through the testimonies of key personnel who participated in pilot programs involving misoprostol. There are many obstacles to scaling-up training initiatives in Afghanistan and other low-resource areas. The analysis concludes that the most crucial factors for scaling-up community-based programs include: more studies analyzing lessons learned

from community driven approaches; stronger partnerships with community health care workers; overcoming barriers like association with abortion, misuse and product issues; and a heightened global and community awareness of the severity of PPH without treatment. These results have implications for those who actively work in Afghanistan to promote maternal health and other countries that may use Afghanistan's work as a blueprint for reducing maternal mortality through community-based approaches.

*Keywords:* Afghanistan, community-based interventions, community-driven, maternal mortality, MDG5, misoprostol, postpartum hemorrhage, reproduction, scale-up

## DEDICATION

I lovingly dedicate this thesis to my husband and best friend, Daniel Cristy, who encouraged me to pursue my educational goals and supported me each step of the way.

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## GLOSSARY OF TERMS

ACCESS Access to Clinical and Community Maternal, Neonatal and Women's Health Services Project

AMA Afghan Midwives Association

AMS Afghanistan Mortality Survey

AMSTL Active Management of the Third Stage of Labor

ANSF Afghan National Security Forces

BCC Behavior Change Communication

BPHS Basic Package of Health Services

CBHC Community-Based Health Care

CCT Controlled Cord Traction

CHW Community Health Workers

DESA Department of Economic and Social Affairs

GHP Gynuity Health Projects

EmONC Emergency Obstetric and Neonatal Care

EPHS Essential Package of Hospital Services

FIGO International Federation of Gynecology and Obstetrics

GII Gender Inequality Index

HDI Human Development Index

HSSP Health Services Support Project

ICM International Confederation of Midwives

LCDD Local and Community Driven Development

MDGs Millennium Development Goals

MMEIG Maternal Mortality Estimation Inter-Agency Group

MMR Maternal Mortality Ratio  
MMRate Maternal Mortality Rate  
MoPH Ministry of Public Health  
NATO North American Trade Organization  
NGO Nongovernmental Organizations  
PPH Postpartum Hemorrhage  
REACH Rural Expansion of Afghanistan's Community-Based Health Care  
TBA Traditional Birth Attendant  
SBA Skilled Birth Attendant  
UN United Nations  
UNICEF United Nations Children's Fund  
VSI Venture Strategies Innovations  
WB World Bank  
WHO World Health Organization  
WGG Working Group on Girls

## Chapter 1

### INTRODUCTION

#### **PURPOSE**

Postpartum hemorrhage (PPH) is a serious medical problem and one of the few obstetric complications with an effective preventative intervention ([pphprevention.com](http://pphprevention.com), 2011). The purpose of this study is to uncover the lessons learned from community-based training programs with the aim of identifying best practices for scaling up awareness surrounding PPH and misoprostol that can translate into pragmatic approaches for future work in Afghanistan and other countries. In particular, the project seeks to understand the factors involved in scaling up community training initiatives: first, lessons learned from existing programs; second, challenges and barriers to successful scale up and suggestions for overcoming these challenges; third, efficacious integration into current program strategies; and fourth, programmatic sustainability given limited funding and or government capacity. In particular, this will be accomplished through a discussion of the established programs and an analysis of the work accomplished in Afghanistan, where the implementation of misoprostol has provided evidence of the efficacy of these approaches to reduce postpartum hemorrhage through core competencies including: community empowerment, institutional capacity building, health technologies, policy advocacy, and reproductive risk analysis (Jhpiego, 2013).

## **OBJECTIVES**

The primary objectives of this project include the following:

- Understand the lessons learned from an existing national training program in Afghanistan to scale up the safe distribution and administration of misoprostol for PPH indications.
- Define determinants of effective scale up procedures.
- Assess barriers to scaling up training initiatives and suggested strategies for addressing those barriers.
- Assess opportunities for integrating misoprostol activities at community levels and in home birth settings.

This project discusses the findings and recommendations from interview commentary, including the methodology, community involvement, distribution mechanisms, monitoring system, education intervention, self-administration concerns, perceived barriers and suggested strategies for addressing those barriers.

## **THE PROBLEM**

Complications of pregnancy and childbirth claim a woman's life in the developing world every 90 seconds (WHO<sup>9</sup>, 2010). The leading cause of maternal mortality globally is from postpartum hemorrhage (UN DESA, 2010). Afghanistan represents some of the most staggering maternal mortality rates with over 347 deaths per 100,000 live births in the Afghanistan Mortality Survey (AMS) 2010 survey area (AMS, 2010). Hemorrhage is responsible for roughly 38% of these deaths (International Journal Emerging Medicine, 2009). Effective, safe prevention exists for PPH indications (Derman et al., 2006). Misoprostol serves as a complementary strategy to achieving safe motherhood and has been shown to effectively address PPH (Sanghvi et al., 2010<sup>1</sup>; Prata et al., 2005, 2009<sup>2</sup>, 2009<sup>3</sup>). Several projects have led the charge in ensuring misoprostol

tablets are available to women who cannot reach a facility, or who deliver without conventional methods, health care workers, or equipment to effectively manage and prevent blood loss (Sanghvi et al., 2010<sup>1</sup>). The International Confederation of Midwives (ICM) and the International Federation of Gynecology and Obstetrics (FIGO) made a joint statement (2006): “In home births without a skilled attendant, misoprostol may be the only technology available to control PPH” (ICM & FIGO, 2007). When other uterotonic drugs are unavailable, misoprostol has been documented to be an effective treatment (Goldberg et al., 2001). However, this growing body of research has yet to be translated into policies and programs in many countries around the world. In part, efforts to broaden women’s access to misoprostol have been stymied by the drug’s complicated history and additional uses (Starrs & Winikoff, 2012).

Since the early 90’s, misoprostol has been used for a myriad of obstetric needs including labor induction and spontaneous medical abortion (Allen, 2009). Yet, evidence to date has demonstrated that misoprostol, an oral tablet, can also play a significant role in preventing and treating PPH indications (Starrs & Winikoff, 2012). What remains unclear, however, is how to scale up community driven programs and translate outcomes in various contexts, particularly at the community level and for home births, where limited or no skilled assistance is available (Coeytaux & Wells, 2011). In addition, there remains to be great inconsistencies in clinical practice, with health care providers utilizing varying dosage and administration regimens (Coeytaux & Wells, 2011). There is also lack of clear guidelines and policies to enable governments to make sound policy and implementation decisions regarding misoprostol at the national level (Coeytaux &



Wells, 2011). Further, there are concerns regarding the alternate use of misoprostol for abortion induction, raising concerns about its misuse for other indications (Starrs, 2012).

To address these concerns, this project aims to elaborate on the outcomes of one such community based study conducted in Afghanistan through Jhpiego and other partners to develop an experience-based understanding and advocacy agenda for promoting misoprostol for PPH indications. In addition, the data obtained from the interviews can be used to direct the scaling up of community based low-tech solutions in other resource poor settings working to address PPH. An important step in preventing maternal mortality and expanding the reach of available treatments is to understand the outcomes of current studies.

## **SIGNIFICANCE OF THE PROBLEM**

Scaling up training, awareness and advocacy programs that provide misoprostol to women could significantly reduce maternal mortality rates. These results have important implications for those who actively work in Afghanistan to promote maternal health and other countries that may use this work as a blueprint for reducing maternal mortality through community-based approaches and low-cost technologies. Misoprostol provides logistical advantages in facility, community and home birth settings and has the potential to address coverage gaps (Starrs & Winikoff, 2012). This project will build upon the current research and studies to understand potential for scaling up community-based training approaches by identifying the key lessons learned from programs already in place. Additional advocacy programs are needed to engender awareness around PPH indications and available treatments. Without additional community-based training

programs to bolster previous work, community mobilization and government policies supporting access guidelines and public sector procurement may prove difficult. The evidence is available. The challenge now is to use the evidence of misoprostol's efficacy and safety to expand the reach of this important PPH treatment and ensure that every woman has access to this lifesaving resource through community based interventions.

## Chapter 2

### BACKGROUND LITERATURE

#### **DRAWING LESSONS FROM HISTORY**

From the historical record of reproductive health several themes emerge. First, there has been a tendency to suppress the discourse on maternal health issues. Second, advances in medical technology have not played a large enough role in improving maternal health. And third, public health approaches that combine health technologies, community involvement, behavior change, capacity building and public policy are needed for substantial gains in reproductive health to be achieved (Middleberg, 2003).

Medical advances and technologies have provided an increasing selection of tools for improving reproductive health. In the early twentieth century, maternal mortality remained high in most Western countries (De Browere et al., 1998). The eventual decline in maternal mortality resulted from widespread use of modern obstetrical methods. As understanding of anatomy progressed, improved surgical techniques surfaced, diagnostic procedures grew and antibiotics and blood transfusion were introduced (Middleberg, 2003). These were important precursors to the decline in maternal mortality. The control of hemorrhage, using ergometrine and oxytocin, combined with blood transfusions dramatically reduced the number of deaths associated with blood loss (Middleberg, 2003). Yet, these medical advances, however important, have not been enough to engender substantial improvements in reproductive health in either developed or developing countries. Rather the available techniques have slowly come to practice, inhibited by the denial of and resistance from medical communities to

adopt new approaches. Consequently, major advances in the medical community and within reproductive health rely on the convergence of multiple actors, events and trends. The introduction of misoprostol to combat postpartum hemorrhage, the single largest cause of maternal mortality, will also rely on convergence of key organizations, policy agendas, and research. To understand the need for such focus, the next section further outlines maternal mortality.

## **MATERNAL MORTALITY**

A maternal death, as defined by the World Health Organization (WHO) in the *International statistical classification of diseases and related health problems*, 10<sup>th</sup> revision (ICD-10) (9), is the death of a woman while pregnant or within 42 days of the end of her pregnancy from any cause related to or made worse by the pregnancy, regardless of the pregnancy duration but not from accidental or incidental causes (WHO<sup>7</sup>, 2010). Every day about 1,000 women die from pregnancy or childbirth related complications (WHO<sup>7</sup>, 2010). Among the women who do experience a complication during childbirth, access to quality obstetric care fundamentally determines the likelihood of mortality (WHO<sup>7</sup>, 2010). As a consequence, the lifetime risk of maternal mortality is greatest where fertility is highest and access to maternal health care is weakest.

**Measures of maternal mortality.** Measuring maternal mortality and progress is challenging because estimates often lie within large ranges of uncertainty due to systematic underreporting and misreporting. Nevertheless, new estimates of maternal mortality are continually gathered to demonstrate progress and highlight needs.

There are two key measures of maternal mortality: the maternal mortality rate and the maternal mortality ratio. The maternal mortality *rate* (*MMRate*) is the number of maternal deaths per 100,000 women in the population (WHO<sup>7</sup>, 2010). And while the global decrease in fertility has yielded a decline in the maternal mortality rate, a decline of 47% from levels in 1990, unintended pregnancies continue to be a major contributor to maternal mortality (WHO<sup>7</sup>, 2010). Afghanistan women reported total fertility rates of 6.6 births against the desired number of children, 4 (Afghanistan Reproductive Health Resources Assessment, 2002). The maternal mortality *ratio* (*MMR*) is the number of maternal deaths per 100,000 live births (WHO<sup>7</sup>, 2010). This ratio serves as a key indicator of the accessibility and quality of health care services. For the most part, maternal mortality ratios have not improved in the developing world. Declines in the lifetime risk of maternal death reflect fertility decreases rather than improvements in maternal health care (WHO<sup>7</sup>, 2010). Table 1, demonstrates the regional disparities in fertility and obstetric care through number of maternal deaths, lifetime risk of maternal mortality and MMR by region of the world. Overwhelmingly according to WHO trends (2010), about 99 percent of maternal deaths are concentrated in the developing world. While these estimates are down from 400 maternal deaths per 100,000 live births in 1990 to 210 in 2010, the maternal mortality ratio in developing regions (240) was 15 times greater than developed regions (16) (WHO<sup>9</sup>, 2012).

Table 1

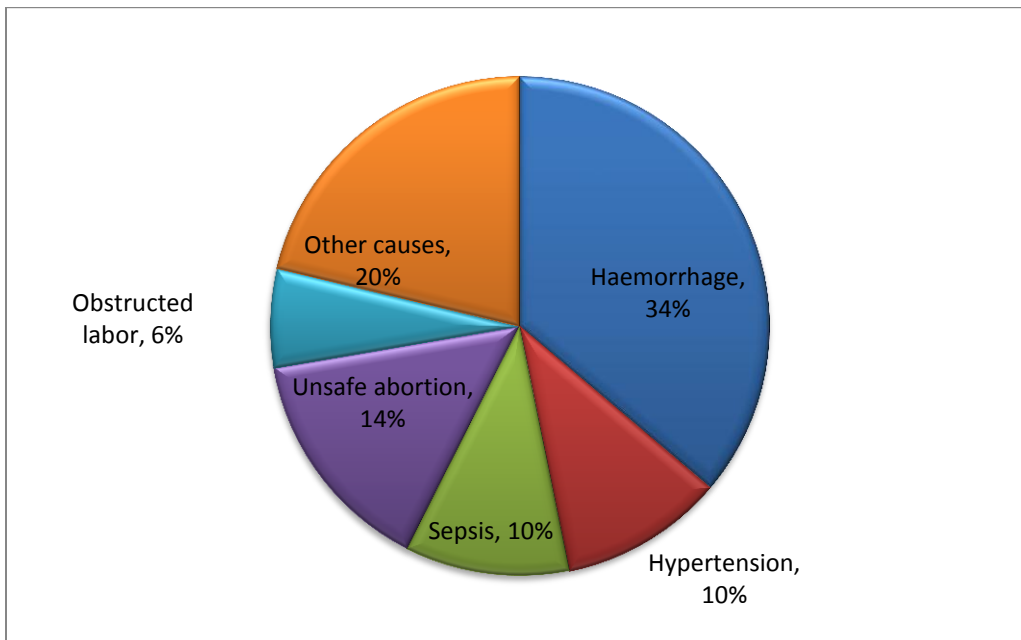
*Estimates of the number of maternal deaths, lifetime risk, and maternal mortality ratio (MMR, maternal deaths per 100,000 live births) by United Nations Millennium Development Goal region, 2010*

<i>Region</i>	<i><u>Maternal Deaths</u></i>	<i><u>Lifetime risk of maternal mortality (1 in n)</u></i>	<i><u>Maternal Mortality Ratio (deaths per 100,000 live births)</u></i>
World	287 000	180	210
Developed regions	2200	3800	16
Developing regions	284 000	150	240
Northern Africa	2800	470	78
Sub-Saharan Africa	162 000	39	500
Eastern Asia	6400	1700	37
Eastern Asia excluding China	400	1500	45
Southern Asia	83 000	160	220
Southern Asia excluding India	28 000	140	240
South-eastern Asia	17 000	290	150
Western Asia	3500	430	71
Caucasus and Central Asia	750	850	46
Latin America and the Caribbean	8800	520	80
Latin America	7400	580	72
Caribbean	1400	220	190
Oceania	510	130	200
Afghanistan	6400	32	460

Source: UN Maternal Mortality Estimation Group (MMEIG) WHO, UNICEF, UNFPA, WB [http://www.childinfo.org/maternal\\_mortality\\_mmrestimates.html](http://www.childinfo.org/maternal_mortality_mmrestimates.html)

**Indirect and direct causes of maternal mortality.** Hemorrhage, puerperal infection, hypertensive disorders of pregnancy, especially eclampsia, obstructed labor, and complications of unsafe abortion, which include hemorrhage, sepsis and shock account for nearly 80 percent of maternal mortality (WHO<sup>10</sup>, 2012). In 2011, WHO health statistics and informatics department published data on both the direct and indirect

causes of maternal mortality for the year 2008. The percentages listed below for causes of maternal death are based on these analyses and data (*Figure 1*).



*Figure 1.* Global distribution of causes of maternal death, 2008.

Source: WHO, Systematic Review of Causes of Maternal Death, 2011.

Hemorrhage accounts for just over one third of all maternal deaths (WHO, 2011). Post-partum hemorrhage, defined as a blood loss of greater than 500 ml after delivery, is the most common cause of death from hemorrhage (WHO<sup>9</sup>, 2012). Death from hemorrhage can occur very quickly (within two hours of birth) and may demand trained assistance to control the bleeding and provide blood transfusions. Complications can occur without warning at any time during pregnancy and childbirth. The role of indirect causes of maternal mortality varies across countries according to the epidemiological framework and ability of the health system to respond appropriately (Li, 1996). Yet, most maternal mortality causes are difficult to quantify, owing to problems with definitions and inadequate records.

**Investing in equitable development for women.** The central challenge to reducing maternal mortality and meeting the MDG goal 5, target 5a with equity is clear: implement community based approaches that harness community empowerment, institutional capacity building, health technologies, policy advocacy, and reproductive risk analysis. Efforts should accordingly be refocused on the poorest and most marginalized women and families while deepening investment for development. (Progress for Children UNICEF, 2010, pp. 10). This next section bolsters the argument that Afghanistan is an appropriate model for developing countries trying to tackle maternal mortality in the face of limited financial resources and despite complicated factors such as: unstable political systems, poor economy, unique gender roles, poor baseline health indices, and ongoing violence.



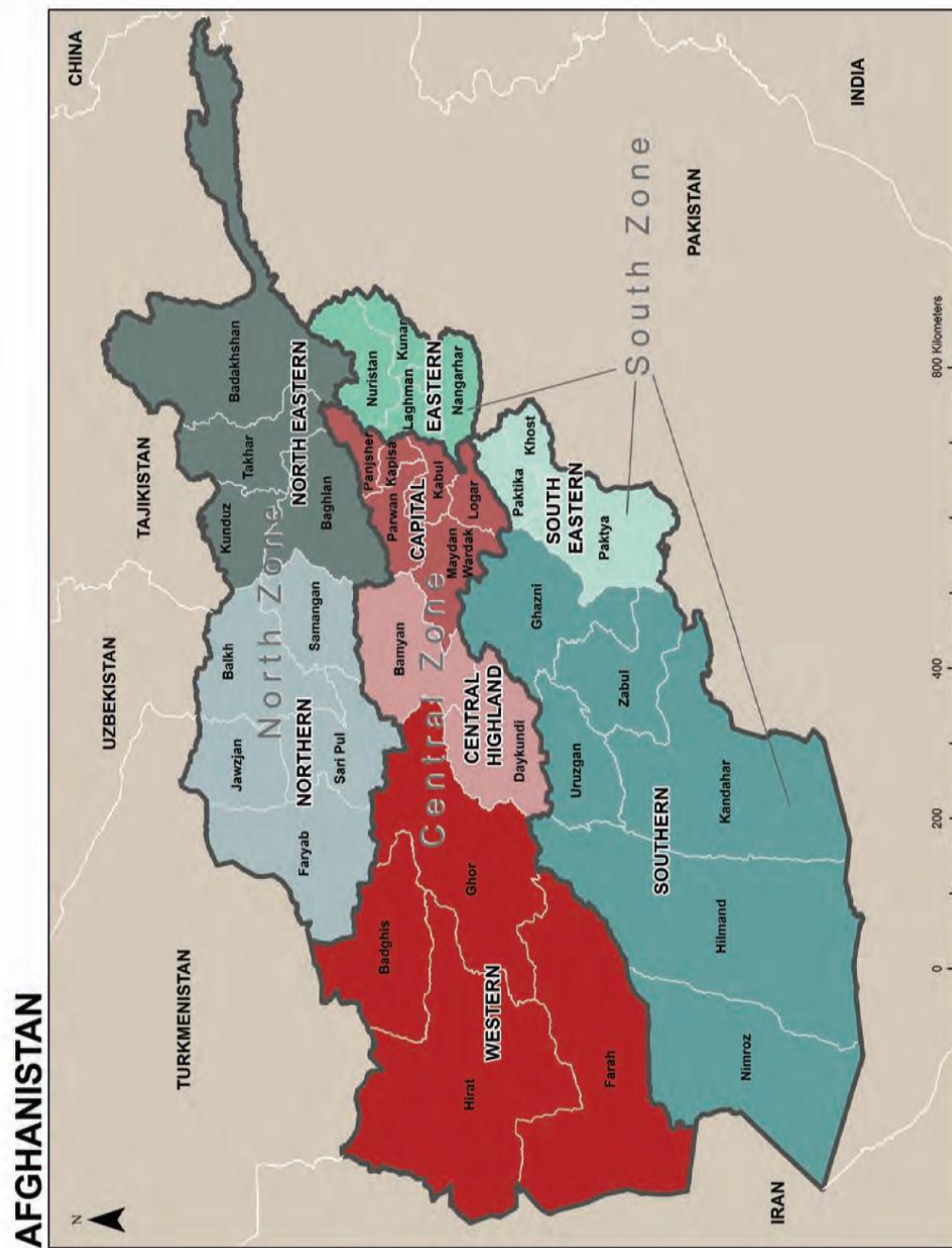


Figure 2. Map of Afghanistan

Source: (Afghan Public Health Institute, 2011)

## AFGHANISTAN

Afghanistan provides an interesting example of a low-income country recovering from decades of strife, having some of the worst health indices in the world (*Figure 3*) and one facing a significant challenge: creating a functional health care system to tackle maternal mortality and other health issues.

Indicator	2000	2006	2010*
Maternal mortality (per 100,000 live births)	--	1800	327
Infant mortality (per 1,000 live births)	165	165	77
Under age 5 mortality (per 1,000 live births)	257	257	97
Life expectancy	41 years	42 years	48
Women with antenatal care (at least once)	4.6%	32.2%	36%
Skilled attendant delivery	6%	18.9%	34%

*Figure 3.* Health indices in Afghanistan

Source: Int J Emerg Med. 2009 June; 2(2): 77–82. Published online 2009 June 5. doi: 10.1007/s12245-009-0106-y

\*Source for 2010 indicators is the Afghan Mortality Survey, 2010.

**Afghanistan's health care system.** The Afghan Ministry of Public Health developed the Basic Package of Health Services (BPHS) in March 2002 to provide a basis for the primary health care system in Afghanistan and establish standards. The BPHS together with the Essential Package of Hospital Services (EPHS) unified priorities, provided direction, expanded basic access, and standardized health facilities classification

systems. (Islamic Republic of Afghanistan Ministry of Public Health 2005: pp 2). Yet, there remain many challenges and bringing about these improvements will require several initiatives and the active participation of the community. Lack of infrastructure and security coupled by human insecurity, economic hardship, difficult access to healthcare services, poor healthcare conditions, and lack of trained healthcare workers, especially women healthcare providers, are all problems that need to be addressed.

**Community-based health care and community health workers.** Community members inherently have better information and understand the local needs, priorities, and dynamics. As such, community participation and community-based health care (CBHC) are critical to improving the health outcomes of communities (Islamic Republic of Afghanistan Ministry of Public Health, 2005; p. 60). CBHC provides interaction between communities and health services, balancing bottom-up control by communities with top-down support from provincial and district officials. CBHC is not new to Afghanistan who adopted an Afghan-specific form of CBHC following a national conference in September 2002. The Afghanistan CBHC policy includes a strong, primary role for the community in health services.

Community health workers (CHWs) are the backbone of the BHPS (MoPH, 2012). The CHW promotes healthy lifestyles in the community and encourages appropriate use of health facilities, skilled birth attendants, and resources (MoPH, 2012). More importantly they teach families to recognize the early signs of complications of pregnancy and childbirth, and assist them in making preparations for emergency referral (BPHS Islamic Republic of Afghanistan Ministry of Public Health, 2005). CHWs play

an important role in reproductive health security and are essential for meeting health care standards and scaling up the distribution of misoprostol to treat PPH. In Afghanistan, community engagement has been successfully initiated by several organizations.

**Nongovernmental organizations (NGOs).** NGOs have played a prominent role in Afghanistan since 1979 providing emergency assistance, capacity and peace building, and rehabilitation support for longer term development in health, human rights, education and agricultural programs (CMI, 2012). In relation to maternal health, several NGO's have played a prominent role in Afghanistan: VSI (Venture Strategies Innovations) USAID (United States Agency for International Development), and Jhpiego. This section briefly outlines some of their work.

***Venture Strategies Innovations (VSI).*** Working with the MoPH to gain acceptance for misoprostol, VSI has conducted operations to establish distribution and pricing strategies as well as advocate product registration for PPH prevention and treatment (Coeytaux & Wells, 2011).

***USAID.*** Health sector assistance in Afghanistan, largely provided by USAID (over 15 billion dollars since 2002), has been aimed at expanding access to basic public health care, including rehabilitation and construction of more than 600 clinics and training of over 10,000 health workers (USAID, 2011).

USAID health projects also address specific health concerns and have placed priority on services that provide security for citizens and empower Afghan institutions through initiatives like “Afghan First” to lead in development and reconstruction efforts (USAID 2011). USAID support for midwives training programs has seen an increase

from 468 to more than 2700 trained midwives in eight years (USAID, 2011). In addition, USAID in collaboration with other donor's has accomplished greater access to health facilities; most Afghans now live within two hours walking distance to a health care facility (USAID, 2011).

**Jhpiego.** Since 2003, Jhpiego has been working in Afghanistan as a partner on the Rural Expansion of Afghanistan's Community-based Health Care (REACH) Program, led by Management Sciences for Health. In 2005, a project to reduce mortality from PPH through birth planning and oral misoprostol was begun through Jhpiego partnership with the USAID-funded ACCESS Program. Since then, Jhpiego has expanded its role in Afghanistan and is the lead U.S. technical agency working in women's and reproductive health (Jhpiego, 2012). In order to increase quality, coverage and utilization of emergency obstetric and neonatal care (EmONC), Jhpiego in collaboration with the MoPH, led a national assessment which also supported EmONC training and the establishment of the Afghan Midwives Association (AMA). The country's first professional organization for women, AMA provincial chapters have expanded to 33 provinces and membership has grown to over 2000 (Jhpiego, 2012).

Jhpiego is also involved in the five-year Health Services Support Project (HSSP) with sub-partners Save the Children and Futures Group International (Jhpiego, 2012). This project focuses on improving health care services across 21 provinces in Afghanistan, while increasing the number of skilled female providers, generating community demand for services, and integrating gender awareness and gender-sensitive practices into health service delivery (USAID 2011, Jhpiego, 2012).

As a result of combined efforts of Jhpiego, MoPH and others, the number of deliveries by skilled birth attendants increased from an estimated 8% (2002), 19% (2006), to roughly 34% (2010) as measured by a national household survey and the Afghan Mortality Survey (AMS, 2010). Further evidence has demonstrated, under ACCESS, that misoprostol is an effective treatment for PPH. In light of these favorable results, the MoPH has asked Jhpiego to gradually expand efforts under HSSP to protect 20,000 deliveries from PPH in five of the most remote provinces in Afghanistan. Expansion efforts, in part will largely depend on funding availability (Jhpiego, 2012).

**Financial state.** Understanding that improvements in maternal and reproductive health have a potential impact and a cost, it is important to understand these outcomes. The National Reproductive Health Strategy for Afghanistan highlights the need to implement appropriate costing strategies. The Maternal Neonatal Program Index was carried out in Afghanistan in 2005 to demonstrate the significance given to various programmatic inputs (National RH Strategy, 2006). This was followed by a costing study to demonstrate *real costs* associated with various activities. The costing tools allow planners to have a deeper understanding of how changes in maternal services can prevent maternal mortality and at what cost (Foreign Assistance, 2012).

**Transformation decade and impacts.** With the imminent withdrawal of American forces scheduled for 2014, there are expected security and financial issues facing Afghanistan (Moore, 2012). At the Kabul and Lisbon Conferences in 2010, NATO (North American Trade Organization) and the Afghan government agreed that responsibility for the safety and security of Afghans would be transferred to the Afghan

National Security Forces (ANSF) by 2014 (World Bank, 2012). In addition, Afghanistan is expected to experience development transitions as civilian and international aid is shifted to other priorities (Moore, 2012). In fact, the World Bank (WB) announced a gloomy forecast of an estimated \$6-7 billion deficit in 2014 for Afghanistan (World Bank, 2012). Clearly these deficits and lack of financial resources will have an impact on humanitarian needs including maternal health.

With respect to health services, these reports recognize that delivery is mainly supported by NGOs, contracted by the MoPH and funded through development and external budgets. World Bank estimates demonstrate that continued funding beyond the transition will require tough choices on services that the Afghan government can no longer afford (World Bank, 2012). Further these estimates show that any significant drop in external funding of the development and subsequently health budget would pose serious threats to health service delivery and maintenance (World Bank, 2012). Without increased government capacity, Afghan may face worse development indicators. As such, community-based, low-cost technologies may provide potential solutions if they are properly aligned with the government's planned justification, adopted by the community, and contribute to strengthen nation-state capacity within health care services. This next section provides information on one such technology and demonstrates that community level distribution and administration of misoprostol may provide salient solutions to the most prominent causes of maternal mortality.

## MISOPROSTOL

Clinical research has the potential to advance knowledge in the use of technology and inform decisions based on the health benefits of such technology. In the past decade critical attention has been placed on reducing maternal mortality rates focusing on resource poor settings. In particular, research on the gynecological indications of the use of misoprostol, has taken center stage. Numerous studies have demonstrated the efficacy of misoprostol in the management of PPH when taken orally immediately following childbirth (El-Refaey et al., 1997; Hoj et al., 2005; Derman et al., 2006; ICM & FIGO, 2006). And although several studies are still ongoing some countries have already begun to translate research into practice. This section provides information on current methods for managing PPH indications and misoprostol studies which evaluate the efficacy of misoprostol versus oxytocin, administration in hospital and community-based settings, and overall safety. Specific focus will be placed on studies aimed at understanding perceived barriers and whether misoprostol can be administered at the local level, within communities and with limited skilled intervention or by women themselves.

**Current methods for management of PPH.** Predominantly, active management of the third stage of labor (AMSTL) substantially reduces the risk of PPH. AMSTL has been defined as intramuscular administration of 10 IU of oxytocin, controlled cord traction (CCT) and fundal massage after delivery of the placenta (Prendiville et al., 2000). A 62% reduction in the risk of PPH has been associated with AMTSL according to a meta-analysis by WHO, FIGO, International Confederation of Midwives (ICM) who recommend that AMTSL be provided for all vaginal births (ICM and FIGO, 2003; ICM



and FIGO, 2006). Currently, the most widely used agents for uterotonic therapy include oxytocin and ergometrine which require parenteral administration and therefore, the necessary skills and equipment, including sterile needles and syringes, to inject the solution safely (Sanghvi et al., 2010<sup>1</sup>). In addition, ergometrine requires refrigeration, dark storage, and cannot be used in the 10%-15% of women who have hypertension in pregnancy (Sanghvi et al., 2010<sup>1</sup>). Oxytocin may be inactivated if exposed to high ambient temperatures and has minor adverse effects.

Misoprostol, unlike oxytocin and other uterotonics, is relatively inexpensive and safe, has a long shelf life, may be taken orally, and remains stable at room temperature (Sanghvi et al., 2010<sup>1</sup>). In addition, misoprostol is a methyl ester of natural prostaglandin and “is well absorbed from the stomach, appearing in the circulation within 90 seconds, and undergoes rapid de-esterification to its biologically active metabolite, misoprostolic acid (Justus et al., 2005 p. 547-553). As such several studies have effectively proven misoprostol to be “clinically equivalent to oxytocin when used to stop excessive post-partum bleeding” (Blum 2010<sup>1</sup>). Further, Langenbach (2006) conducted a meta-analysis of all randomized control trials (RTC) that tested the efficacy of misoprostol for PPH indications against alternative methods and concluded that, when there are no other alternatives, misoprostol provides viable and potent solutions. It may be summarized based on these clinical trials and other studies that misoprostol is an appropriate alternative for treating PPH when oxytocin is unavailable, as in low resource countries.

**Perceived barriers.** There are numerous perceived barriers to and complexities of introducing misoprostol for PPH prevention and treatment. These barriers range from

issues, such as the lack of global accord, product availability, and clear research findings, to broader sociopolitical concerns, such as a lack of willingness to empower women, fears about safety and side effects and association of misoprostol with abortion.

***Lack of global accord and guidelines.*** There is a lack of consensus surrounding the WHO guidelines for the use of misoprostol for PPH prevention and treatment (Frye, 2011). Compounding this issue, are the unclear WHO statements regarding misoprostol and its exclusion from the WHO Model Essential Medicines List (EML) for PPH specific indications. The EML is “an inventory of medicines that treat pressing health concerns and that should be available to the population” according to Blum, Gynuity Health Projects (GHPs) (Frye, 2011). At the time of launch in 1977 by the WHO, only 12 countries had their own EML lists. Now about 80% of countries have adopted national lists as a basis for procurement and supply of medicines and to guide local medicine production (Frye, 2011). In 2009, WHO’s position on misoprostol was one of caution withholding EML recommendation because potential benefits and harms were unknown (WHO, 2009). In 2010, WHO recommended that AMTSL be offered to all women during childbirth to prevent PPH. This package of interventions included the recommendation of misoprostol in settings where other uterotonics like oxytocin are not available (WHO<sup>6</sup>, 2009). Further, WHO stated that it does “not recommend distribution of misoprostol to community level health workers or women and their families for routine or emergency use” (WHO<sup>6</sup>, 2009). In 2011, misoprostol was added to the WHO Model EML list for the prevention indication of PPH, validating its important role in reproductive health. However, the PPH treatment application (with an 800mcg sublingual regimen) was not

accepted for the 2011 EML meeting. The committee denied the GHP application, citing a lack of evidence surrounding safety (Frye, 2011; WHO<sup>8</sup>, 2011). Other global and national clinical guidelines such as FIGO and ICM, American College of Obstetricians and Gynecologists (ACOG), and Royal College of Obstetricians and Gynecologists (RCOG), have also addressed misoprostol for PPH treatment (ICM, FIGO, 2007; ACOG, 2006; RCOG, 2009). While countries are not bound by WHO recommendations and other clinical guidelines, they are greatly influenced by them. Not having cohesive global guidelines may influence some government officials to prohibit use and thwart community based approaches involving misoprostol until such cohesive statements are made (Coeytaux & Wells, 2011).

***Product availability.*** Considerable attention has been placed on registering misoprostol for the specific task of preventing and treating PPH. Registration can be difficult and expensive (VSI, 2011). Registration for PPH indications is challenging first and foremost because misoprostol is not registered in the United States or the United Kingdom for that indication and many countries look to these nations as a basis for registration (Frye, 2011). In addition, companies are reluctant to register their products for a drug with controversial indications (Coeytaux & Wells, 2011). Still registration has been viewed as an important step toward increasing misoprostol's availability (VSI, 2011).

***Product quality and packaging.*** In a study by Concept Foundation, supported by GHPs to collect and analyze misoprostol quality measures, 74 samples were collected from eleven countries (Hall, 2011). Findings indicated that 34 out of 74 samples

contained less than the industry standard, 90 and 110% of the labeled content in the misoprostol products (Hall, 2011). Of these, 8 contained less than 20% of the labeled content and two were likely counterfeits containing zero misoprostol content (Hall, 2011). In addition to content analysis, the samples were tested for longevity. After one year, misoprostol content in 18 out of 20 samples was found to be less than the regulated content (90-110%); 7 of these had less than 20%. In addition, packaging quality is an important factor. Concepts found more degradation over time with aluminum-plastic blister packs compared to aluminum-aluminum blister packs (Hall, 2011). Results indicated that over time the quality of a product may be impacted by heat and humidity. And to date, no tests have been conducted to determine the impact on misoprostol's effectiveness given purity and quality concerns (Hall, 2011). Two doses of misoprostol tablets are needed –a 25mcg dose labeled for induction of labor as well as a 200 mcg tablet for all other indications (Coeytaux & Wells, 2011). The packaging should include instructions for reproductive health indications and the number of pills per package should be appropriate to the indication. Without different packaging or clear instruction labels, misoprostol has the potential to be taken incorrectly (Hall, 2011). Overall, the quality of misoprostol is unknown and this may be a barrier if there is a lot of substandard product on the market. Additional studies are needed to understand the life-cycle of misoprostol and best practices for manufacturing production and packaging. Further, the emphasis on generic manufacturers and products may come at the expense of product quality (Coeytaux & Wells, 2011).

***Fear of women's empowerment.*** Gender and the status of women in many countries remains a barrier to the use of misoprostol. In some settings, the low status of women contributes to the desire to control women and fear of giving women control over their reproductive decisions. Studies have revealed that several people play a role in the decision-making process concerning reproductive health and the use of misoprostol for PPH treatment and prevention. In Bangladesh, a community-based pilot intervention study revealed that women who used the tablets often made the decision themselves (Hashi, 2010). On the other hand, women who elected to forgo the misoprostol tablets were frequently prevented from using them by family members or other influential individuals (Hashi, 2010). This information informs health care administrators and other policy advocates that additional family members should be targeted in behavior change communication (BCC) activities, so exposure to important information about misoprostol and PPH is more effective.

To overcome these empowerment fears, women's organizations need to play broader roles in disseminating information about misoprostol, its intended use, availability, and role in reducing PPH. In addition, since access to skilled health care providers is often limited or challenged, women need to be targeted as providers of their own care. BCC activities need to also target family members and other influential individuals who are likely to be present at the birth. Considering most births (80%) occur at home, advocacy should emphasize the education and "task-shifting" to ensure staff and women themselves are authorized to use uterotonics like misoprostol (Coeytaux & Wells, 2011, p. 15). In order to make these strategies more viable, additional research is needed

to answer concerns associated with the safety and effectiveness of this empowerment, community driven approach.

**Safety.** Many studies voice concerns regarding the safety and side effects of misoprostol given its broad range of uses (Table 2). If used improperly, misoprostol can cause uterine rupture or augmentation of labor (Starrs, 2012).

Table 2

*Use and Indications for Misoprostol in Reproductive Health*

<ul style="list-style-type: none"><li>• Cervical priming</li></ul>
<ul style="list-style-type: none"><li>• Induced abortion</li></ul>
<ul style="list-style-type: none"><li>• Labor induction</li></ul>
<ul style="list-style-type: none"><li>• Uterine evacuation after failed pregnancy</li></ul>
<ul style="list-style-type: none"><li>• Prevention and treatment of PPH</li></ul>

Source: Adapted from International Journal of Gynecology and Obstetrics, (Starrs 2012).

In addition, the use of misoprostol has been associated with side effects including: fever, chills, and shivering. Unusual rates of high fever were associated with participants in Ecuador who received high doses, 800mcg of sublingual misoprostol for PPH treatment (Starrs, 2012). Better information about optimal dosage and delivery method could reduce adverse side effects and safety concerns. Lumbiganon et al., (1999) documented that adverse effects of misoprostol are related to correct dosage (600 ug). And additional research is needed to better understand the implications of using repeat doses in the event that a woman conceives after PPH treatment. Currently there is insufficient knowledge of

safety surrounding multiple treatments of misoprostol for PPH treatment and prevention. Yet according to a Family Care International study: “*Mapping Misoprostol for Postpartum hemorrhage: Organizational Activities, Challenges, and Opportunities*,” some would be quick to point out that “many people are more concerned about what might happen with an intervention (i.e., side effects) than what might happen without an intervention (i.e. maternal death)” (Coeytaux & Wells, 2011).

***Ethics.*** For every woman delivering, the risk is heightened after the baby comes. In the industrialized world, it has been almost a century since drugs were introduced to stop post-partum bleeding and curb this risk (Coeytaux & Wells, 2011). Misoprostol, a simple 10-cent tablet that requires little skill to administer and can be stored within normal temperatures has induced a myriad of controversy for its multi-reproductive indications (Coeytaux & Wells, 2011). Some countries see the introduction of this drug as a moral danger. In the Philippines, misoprostol has been banned from use (Coeytaux & Wells, 2011). Countries are afraid of its potential misuse. Other groups, however, advocate its ability to combat PPH in developing countries. The WHO has stated that additional studies are needed to better understand dosage and timing considerations for safety (WHO<sup>8</sup>, 2011). WHO’s department of reproductive health and research, medical officer, Gulmezoglu stated that “In medicine, there are things that look like they may be so straightforward, and they turn out not to be...and that can cause hundreds of thousands of deaths. That’s what we’re trying to avoid here” (Abraham, 2010).

In many cases, politics undermine efforts to make misoprostol widely available (Hazem, 2010). Hazem, an Egyptian-born scientist, obstetrician and gynecologist

emphasizes that “no other pill has the power to force a global reckoning on the ties between a mother’s well-being and a woman’s reproductive rights” (Abraham, 2010). International commitment to improve maternal health draws the line with initiatives that may cause abortion. Those in the developing world want to follow the lead of the West, and no Western country has approved misoprostol for PPH indications (Abraham, 2010). In addition, Western patients have other options so there is no push for such a drug. Yet, Prata (2010) signals the urgency for introduction of this drug. She states, “In Africa, it will take 80 years for every woman to deliver with a skilled attendant. Do we wait until we have a midwife or a gynecologist for every woman? Women are dying.” Prata continues, “I don’t need 100 studies to tell me that this drug can stop the bleeding” (Abraham, 2010). What should be considered is how many women will die while international groups and leaders discuss the ethics of community-based distribution of misoprostol. The clock is ticking and in the meantime women are dying (Prata, 2010).

***Abuse of misoprostol and abortion.*** At the heart of ethical discussions lies the indication of misoprostol for abortion. Several groups are concerned that misoprostol may be used for abortion and hinder the introduction of this drug for postpartum indications (Coeytaux & Wells, 2011). Acting on this fear, several governments (e.g., Brazil, Philippines, Thailand, and Nicaragua) have restricted misoprostol sales within the private sector due to self-induced abortions (Coeytaux & Wells, 2011). Many of the decision makers are not aware of misoprostol’s multiple uses. As such there is a need for transparency surrounding intended uses and indications for misoprostol.



***Other barriers.*** Scant resources for PPH interventions and for misoprostol generate concerns that governments can sustain resources to pay for prevention strategies, especially at greater community levels. Further, training doctors, health care workers, and women about misoprostol may be costly and difficult. Not all doctors are aware of misoprostol's PPH indications and may be relying on what they learned in medical schools regarding the use of oxytocin (Coeytaux & Wells, 2011).

**Community-based distribution of misoprostol.** Delivering in a hospital or health care facility is not yet a feasible option for many women in developing countries, thus placing women at risk for PPH. Strategies, therefore, need to address these realities and focus on community-level interventions to meet women where they are and based on the services they have access to. Evidence suggests that misoprostol is safe and effective when used at the community level (Rajbhandari et al., 2010; Sanghvi et al., 2010<sup>1</sup>). Pagel et al., (2009) used mathematical models to demonstrate that coordinated efforts of community-based distribution of misoprostol and health care system capacity strengthening could “prevent 32% of maternal deaths” attributed from PPH indications (Grossman et al., 2010). Such mobilization will increase community access, knowledge and participation and is vital to the safety of women needing treatment. A recent study by Prata et al., (2012) uncovered that when information about postpartum hemorrhage and misoprostol is successfully disseminated at a community level there are high levels of comprehension of intervention messages resulting in higher uptake of the health intervention and potential for coordinating policy change. Even in circumstances where

high levels of community mobilization cannot be achieved, evidence suggests that modest levels of involvement can have significant impacts (Prata et al., 2012).

***Mayer Hashi project.*** The International Federation of Gynecology and Obstetrics and the International Conference of Midwives have jointly recommended the use of misoprostol for home births without skilled attendants (ICM and FIGO, 2006). In 2008, the National PPH Prevention Task Force, the Directorate General of Health Services, the Directorate General of Family Planning, and the Mayer Hashi Project joined efforts to pilot community-based distribution of misoprostol for PPH prevention in Tangail District, central Bangladesh using health care workers from government and NGO organizations (Harper, 2010).

The project was conducted between November 2008 and June 2009 and included a misoprostol policy and implementation plan, training curriculum, educational materials, checklists and tools, and supply of misoprostol tablets. Workers were trained in the need for community-based intervention, PPH indications, identification and registration of pregnant women, follow-up processes and how to educate women about PPH, misoprostol, and safe motherhood practices (Harper, 2010). A special three-tablet packet (200mcg misoprostol/tablet) with instructions in the local language indicating needed dosage and administration were provided. Communication activities were conducted with pregnant women, family members, and other key community individuals regarding PPH, delivery complications, advantages of hospital delivery, and the use of misoprostol for PPH treatment and prevention after home delivery (Harper, 2010).

Additional community awareness was generated through the use of stickers placed on homes, which identified pregnant women within the community and reminded the woman and family about the need to immediately take misoprostol following birth. During the trial period, 12 961 out of 19 497 registered pregnant women received misoprostol tablets at or after 32 weeks of pregnancy. Of these, 9 228 (92%) took the tablets after delivery (Mayer Hashi Project<sup>2</sup>, 2010). Eight women died as a result of childbirth; 5 from PPH (4 of these refused to take misoprostol) (Mayer Hashi Project<sup>2</sup>, 2010). Of the women who used misoprostol as instructed, there were no fatalities. After the pilot period, project evaluators interviewed some of the women who had taken misoprostol (16) and some who had not (15 women) (Harper, 2010). Knowledge about PPH varied and misconceptions about “bad blood” needing to be cleansed after pregnancy need to be addressed (Harper, 2010). Overall, women demonstrated a good basic knowledge of misoprostol although some were confused on when to take the tablets (i.e. before or after delivery of the placenta) (Mayer Hashi Project<sup>2</sup>, 2010). These trials indicated that pregnant women and health workers widely accepted the use of misoprostol for PPH indications and that the program model can be expanded beyond the trial area. Further findings demonstrated that additional outreach is needed to secure community members’ understanding of postpartum bleeding (Harper, 2010).

***Nigeria.*** Considering the strong role traditional birth attendants and other influential community members play in decision making processes, it is important to involve these individuals in educational and communication activities. Nigeria, in 2010, became the first country worldwide to endorse guidelines for the use of oral misoprostol

for PPH indications at the community level (VSI, 2011). The pilot intervention (2009) in northern Nigeria provides a model for other low-resource settings where home-based deliveries are the norm. The aim of the study was to demonstrate the importance of community mobilization and the distribution of misoprostol (Prata, 2012). In this study, synergies emerged through community mobilization—even low levels of participation, that were relevant to intervention uptake (Prata, 2012). When community members learned that the threshold for PPH was 500 ml of blood loss, they identified a local rubber cup used for water, the *moda*, as a useful reference for understanding volume. Using a community recognized cup provided clear representation of when a woman had lost too much blood and was facing a serious situation in which called for emergency care (Prata, 2012). They also identified other culturally appropriate items like the *hijab*, head scarf for Muslim women, head ties for Christian women and *butas*, or water kettles, for Muslim men. These items were inscribed with simple reminders about misoprostol dosage: ‘Take three tablets of misoprostol immediately after birth to prevent postpartum hemorrhage’ (Prata, 2012). These items were frequently cited by women interviewed after the study as important aids in disseminating information about PPH indications and treatment. In addition, these results beckon scientific support for policy dialogue surrounding medical guidelines for misoprostol use worldwide and as part of the broader educational campaign (Prata, 2012).

**Jhpiego.** Another study, conducted by Jhpiego, VSI, and Save the Children (2009) addressed the safety, acceptability, feasibility and effectiveness of misoprostol distribution through community channels for PPH indications at home births in Kabul,

Afghanistan (Sanghvi et al., 2010<sup>1</sup>). Providing skilled assistance to all women in Afghanistan is many years away as many women live in rural areas and do not have access to skilled birth attendants or facilities (Sanghvi et al., 2010<sup>1</sup>). As such maternal mortality reduction strategies to tackle PPH prevention and treatment “must consider what can be achieved at the community level, beyond the reach of skilled professional providers” (Sanghvi et al., 2010<sup>1</sup>). This nonrandomized experimental control design was aimed at evaluating community education about PPH prevention in rural Afghanistan and to assess whether misoprostol could be self-administered for PPH indications during home births (Sanghvi et al., 2010<sup>1</sup>). Approved by the Afghanistan Ministry of Public Health, Technical Advisory Group, Essential Drug Board, and Ethical Review Board (no. 3583222, MoPH Afghanistan, February 23, 2006), the study was conducted between June 2005 and August 2007 in three phases and involved key stakeholders throughout these stages. Findings indicated that community-based education and distribution of misoprostol through “semi-literate” community health workers is safe and effective, and this strategy “should be considered for other countries where access to skilled attendance is limited” (Sanghvi et al., 2010<sup>1</sup>). Further, this approach did not discourage use of skilled care and rather encouraged identification of and skilled provider use through educational messages. This study also demonstrated the successful approach of involving husbands and other influential family and community members in the educational process (Sanghvi et al., 2010<sup>1</sup>). Importantly, these approaches offer women a strategy for addressing mortality reduction today.

Accompanying this study, in partnership with ACCESS and USAID, Jhpiego also created a Program Implementation Guide (2009) to provide reproductive health administrators and managers with a “reality-based” guide to aid in setting up community-based, country-specific misoprostol programs (Sanghvi et al., 2010<sup>2</sup>). The approach considered cost effectiveness, feasibility, and evidence-based practices for PPH indications that would improve women’s health worldwide (Sanghvi et al., 2010<sup>2</sup>). The guide transfers available research to practical solutions that address the fundamental challenges of beginning and implementing health care programs. The program focuses on providing community health volunteers with information and training to advocate misoprostol use (Sanghvi et al., 2010<sup>2</sup>).

The conclusion across studies indicated that misoprostol is considered to be “safe, effective and feasible” in community-based administration where access to skilled attendance is limited (Sanghvi et al., 2010<sup>1,2</sup>; Ministry of Public Health, Zambia, 2009; Prata et al., 2005, 2009<sup>1</sup>, 2012). Most findings also acknowledge the need for additional misoprostol studies surrounding self-administration and CHW distribution (Prata, 2006).

This project greatly draws on the framework created by the above mentioned pilot interventions, research programs, and implementation guide, and suggests an expanded role for women in securing self-sustaining solutions to their health problems given the shortage of health care workers and barriers to receiving medical care within hospital settings. In order to scale-up efforts alternative solutions need to be explored where women are empowered to administer misoprostol without skilled assistance and additional community driven programs are implemented.

This study aims to further this agenda by adding to the discussion regarding misoprostol's use within the community and by women themselves. Women are capable of using misoprostol safely with access to appropriate information. This next section provides a deeper understanding through discussion of relevant theories.

## **THEORETICAL DISCOURSE**

A fundamental aspect of human development is the potential to live a long and healthy life. Enormous progress has been made in improving health and survival around the world during the second part of the twentieth century. Life expectancy at birth for the world population rose from 48 in 1950-1955 to 68 years in 2005-2010 (DESA, 2012). However, these improvements are not shared across countries and regions and there remain wide disparities among progress indicators. These differences are largely a reflection of the inequalities associated with access to food, safe drinking water, sanitation, health care and other basic human needs. They also illuminate differences in risk factors, behavioral choices and societal contexts that impact individual survival including disparities between urban and rural areas, between men and women, and between rich and poor. (United Nations Department of Economic and Social Affairs/Population Division 1 *World Mortality Report 2009*). The reduction of mortality, particularly child and maternal mortality, is an agreed upon target laid out in the Programme [sic] of Action of the International Conference on Population and Development and in the United Nations Millennium Declaration.

Understanding reproductive health needs is best juxtaposed within theoretical discourse. This section discusses the role of gender and the Local and Community Driven

Development (LCDD) approach for reproductive health. In particular, this discussion will incorporate the relevant theories as they bolster the prevailing themes and discuss maternal health indicators.

**Role of gender in reproductive health.** Complexity within household decision-making processes is commonly ascribed to the differences in gender roles of women and men and becomes a powerful force in reproductive health. The Gender Inequality Index (GII) is a composite measure of inequality in achievements experienced by men and women in three dimensions: reproductive health, empowerment and the labor market. In Afghanistan the GII is 0.707 compared to the United States at 0.299 (Human Development Report, 2011). Gender discrimination compounds poverty induced vulnerability and has negative consequences for both men and women. Gender affects reproductive health outcomes in many ways:

*Access to assets:* Gender differences impact girls and women's ability to access education, health care services and obtain financial security (Middleberg, 2003; Breneman & Mbuh, 2006). These are powerful determinants of fertility and other health outcomes (Middleberg, 2003). "Financial or material dependence on men means that women cannot control when, with whom and in what circumstances they have sex" and puts women at a "serious disadvantage" (Breneman & Mbuh, 2006). Further, they may not be able to travel without a male relative companion, limiting their ability to access care.

*Decision-making about reproductive health:* Many women, deeply influenced by the prevailing idea that they should bear and raise children, may feel constrained by social



and cultural conditions (Middleberg, 2003). Decisions to use health care assets may rely on the agreement of a husband or other family member. Women may not be able to independently concur to contraception or obstetric care.

*Value placed on women's health and life:* Girls and women in many societies are given little value and may negatively impact household decisions to allocate resources in saving their lives (Middleberg, 2003).

*Expectations about reproductive behavior:* Societal pressures placed on women may impact the number of children and importance placed on having a particular sex, especially sons (Middleberg, 2003). This creates additional risk of unwanted and even dangerous pregnancies.

*Violence and the threat of violence:* An increased awareness of how traditional gender values in many countries can have both direct and indirect results on reproductive health has shed light on the most egregious forms of violence including female infanticide, female genital mutilation, molestation, rape, and abuse (WGG, 2000). The Working Group on Girls (WGG) acknowledges that adolescent girls:

Face a high possibility of developmental and life-threatening dangers: early marriage, early pregnancy and maternal mortality, trafficking, sexual and other interdependent high-risk behaviors... girls also face the possibility of being forced to become heads of households while still children (WGG, 2000).

Further the very threat of violence can influence pregnancy outcomes, use of contraception and safe sex practices (Middleberg, 2003). Thus enhancing reproductive security and determining correct reproductive health agendas relies on curbing the negative impacts of gender discrimination and empowering women. Community based

approaches must understand and address the dynamics of household decision-making by raising consciousness about reproductive health needs, helping women mobilize resources, and support grass-roots efforts and essential health service packages. However, before considerable measures may be made or health agendas suggested, one must better understand the confluences of theoretical background and pragmatic policy agendas on maternal mortality and reproductive health issues.

**Local and community driven development (LCDD).** Also central to understanding the correct use of misoprostol for PPH indications is the Local and Community Driven Development (LCDD) approach that offers control of development decisions and resources to community groups and representative local governments (World Bank, 2009). Local projects are chosen to improve not only people's incomes but promote their empowerment and governance capacity.

LCDD operations have demonstrated effectiveness at delivering results through local and community-driven programs tailored to meet community needs and likely to be maintained and sustained. In addition, according to the World Bank, LCDD has “proved an effective way to rebuild communities in post-conflict and post-disaster situations...by restoring trust at a local level and rebuilding social capital” (World Bank, 2009) LCDD ensures that affected communities are involved in designing recovery programs and that resources are effectively and transparently used. Achieving national coverage beyond the development enclaves is a major challenge for LCDD in terms of scale (World Bank, 2009). According to the Bank, the LCDD agenda remains relevant because of three deliverables:

- The efficient use of public resources by those who need them most. The approach gives communities and local governments the authority and resources to undertake initiatives in sectors that will produce the highest impact at lower cost than centrally managed programs.
- The empowerment of communities to plan and manage their own economic and social development.
- The possibility of better local governance through transparent and accountable local decision-making.

(Source: World Bank, 2009)

Community driven development requires a programmatic approach that combines multiple functional groups and sectors. In order to operate LCDD on a larger scale, changes in the inter-governmental and fiscal systems as well as the transfer of real power, resources, and accountability to local levels is needed. Many LCDD projects have paved the way. Yet these discrete LCDD projects face the challenge of scaling up efforts into sustainable national programs that build governance and state capacities.

This project aims to better understand the best practices and underpinnings, analysis and lessons learned, and guidelines for scaling up community based implementation programs and policies that fit the individual contexts of countries and localities.

The role of communities has evolved from when development practitioners consulted with communities, to the participation of communities in specific aspects of programs, to the eventual empowerment of communities to define and manage development programs in partnership with local governments or by themselves (World Bank, 2009). This shift of power, decision-making, and development management away from central to local authority levels has been slow. In Afghanistan, community engagement has been successfully initiated by several agencies. The next section explores these programs further through proposed methodology.

## Chapter 3

### METHODOLOGY

Research should lead to the understanding of how to successfully scale up community based approaches on the correct use of misoprostol to treat PPH postpartum. What are the key determinants of successful community-based programs? What are the lessons learned from previous studies? What are the challenges and barriers to successful scale up? How can these barriers be addressed? How can the innovation and efforts to scale-up the approach be integrated into existing health care programs? In order to develop answers to these questions, a concurrent triangulation strategy employing an analysis of documents with survey interviews and a case study analysis methodology will be used.

#### **THEORETICAL METHOD OF INQUIRY**

Quantitative analysis provides concrete, specific studies where variables are “tightly controlled through design or statistical analysis” and thus provides “measures or observations for testing a theory” and ultimately leads to “meaningful interpretations of data” (Creswell, 2009: 145). Case studies are effective in providing “holistic and meaningful characteristics of real-life events” (Yin, 2009: 4) and the lessons learned from the studies are intended to provide generalizations for other research contexts (Yin, 2008; 6). The concurrent triangulation approach is the most familiar of the mixed methods and in general “offset[s] the weaknesses inherent within one method with the strengths of the other” (Creswell, 2009: 213). In addition, this method allows the quantitative and qualitative data to be collected concurrently, “happening in one phase of the research

study” (Creswell, 2009: 213). Given the geographic limitations associated with studying Afghanistan, simultaneous data collection will be advantageous. An additional advantage to the method is that it can result in “well-validated and substantiated findings” and results in shorter data collection time periods (Creswell, 2009: 213-214). A limitation to the study is the effort and expertise required to study a phenomenon with both quantitative and qualitative methods and the difficulty in comparing the results as researchers may be “unclear how to resolve discrepancies that arise in comparing the results” (Creswell, 2009: 214). Yet there is emerging literature on this method that can address these concerns (Creswell & Plano Clark, 2007). In this study, the data was merged during the discussion section and the qualitative quotes from the interviews were used to support the quantitative results.

#### **QUALITATIVE METHODS: CASE STUDY**

The work accomplished by NGO’s in Afghanistan provides a case for examining the role of misoprostol in propelling progress towards MDG 5 target 5a, considering that Afghanistan has consistently ranked low in the human development index (HDI) and has some of the most staggering maternal health statistics. Yet, studying the results of Jhpiego’s work alone does not provide enough information to understand the complexities associated with countries experiencing significant maternal mortality rates and their ability to reduce these rates. Thus, an analysis of the testimonies of staff members who have worked on several projects was used to establish a point of comparison. The projects illustrate ways in which health care goals have been targeted at the community level and the use of misoprostol to address PPH indications. Although

certainly not congruent, the obstacles to reducing maternal mortality in each project and across countries share enough similarities to make them prime for comparison, such as they all faced difficulties in access to health care facilities, motivating health care workers, and additional barriers that obscured development altogether. Understanding the outcomes of these studies is an important step in preventing maternal mortality and expanding the reach of available community driven treatments. As such this project is a worthwhile endeavor.

## **SAMPLE AND POPULATION**

This section describes the sample, including the sample size, procedures, and strategies that will be used in selecting participants and procedures that will be employed to gain access to the participants in the study.

**Sampling procedures.** The target research sample consisted of key staff members and health care workers who are nationals of or have lived in the respective countries and held direct knowledge of community-based programs involving misoprostol for PPH indications. It is important to select participants based on their ability to contribute to the phenomena being studied, in this case the expansion of community based programs on the correct use of misoprostol for PPH indications. Yet in most qualitative studies, participants are selected based on their “representation of the population” and ability to be generalized to greater samples (Creswell, 2009). This random selection process of the population at large will not benefit the current study where experience is also a targeted aspect of participant involvement in the study.

Therefore, purposeful sampling was employed to guarantee that the sample was not only representative of the population but also informed on the target phenomena.

Consequently, key participants included medical doctors, Jhpiego staff and other key individuals known to have worked on relevant studies and who have contributed to the literature on these topics. Further, this population was targeted because of their knowledge or perceived knowledge of community-based training programs and misoprostol, assessment of barriers and suggested strategies for addressing those barriers, and familiarity with opportunity to scale up misoprostol activities at community and home birth settings. In addition, a majority of the participants are Afghani and have a deeper understanding of the sociocultural aspects that drive community development in Afghanistan. While it is difficult to determine the needed sample size, for this study 5 participants were included to provide an array of experiences and allow for outliers and information that could not be utilized in the findings. Enough participants were included in the study until the information was found to be saturated and findings redundant.

**Targeted participants.** Working with Byrd, former Jhpiego Country Director in Afghanistan (2008-2012), the researcher made a list of proposed participants for the interview. In addition, the snowball strategy was used to ask participants for names of additional individuals who know something about the phenomena being studied and may be interested in participating. Most respondents named one another when asked for additional participants for this study, reaffirming that although the number of participants was small that the correct persons were included in this particular study.

For this study, the researcher employed maximum variation strategy where diversification in experience with misoprostol and participation in the health care system is critical. Under these criteria, participants are employed by Jhpiego or another NGO working in Afghanistan on misoprostol community based projects and have experience with program implementation, training, or outcomes. In fact, a majority of the participants were Afghani men who are keenly aware of the sociocultural factors involved with implementation. The idea was to ensure that participants had first-hand experience of the phenomena and detailed descriptions of events rather than hearsay. Additionally using the confirmatory sampling strategy, researchers were able to validate facts and events with subsequent interviews that either confirmed or disconfirmed findings (Creswell, 2009). This is one of the ways an interview is corroborated and validated (Creswell, 2009).

Table 3

*Targeted Participants*

Participants	(Targeted Number)
Jhpiego personnel	4
MoPH Officials	2
Medical doctors	2
Health Care Workers	2
Total	10

Note: Table reflects the targeted number of participants in each category. These do not reflect the actual number of participants given the snowball and confirmatory strategies.



## DATA COLLECTION

This section describes the method of data collection and data management procedures. Two data sets were proposed for this study including survey interviews and documents. Given the constraints of time and geography survey interviews were conducted in person using the help of Skype technology. Survey interviews are the recommended choice for case studies according to Creswell and can be conducted one-on-one, via telephone, mail or electronic (Creswell, 2009). For the purpose of this study one-on-one interviews provided in-depth and detailed information from the respondent and allowed for clarification of questions, probing for details and flexibility in structure. In cases where Skype interviews were not possible, participants were given a written version of the interview.

**Gaining access to participants.** Gaining access to participants and permission to gather information was critical to the success of this study. Jhpiego Afghanistan Country Director, Byrd agreed to help determine key participants from Jhpiego, MoPH and other organizations for this study. To build rapport with the participants the researcher contacted interviewees prior to the scheduled interview in order to inform them of the importance of the study and answer any questions or hesitations they may have had regarding participation in the research process. In addition, the researcher explained the confidentiality and anonymity that participants had during the study and the benefits of participation. In this study, participants are given an opportunity to have a “voice” and share their opinions and suggestions for expanding community based projects and role of misoprostol to prevent and treat PPH indications in Afghanistan in a published study.

Further, their experience may contribute to the understanding and effective employment of misoprostol and community based strategies in other countries in the future.

Participants were given the option to withdraw from the study at any time or skip a question should they choose to do so.

Addressing these concerns and making personal contact with participants helped mitigate the hesitations and secure the commitment of participants. Having participants decline or withdraw from the process is a disadvantage associated with individual interviews (Creswell, 2009). In addition, interviews can be time consuming. However, the richness of information obtained from one-on-one interviews far outweighs these disadvantages. In this study, one participant withdrew from the process and another declined to participate. In addition, one participant opted to supplement the Skype interview with written answers and additional documents and papers they had written.

**Interviews.** The interviews were semi-structured with a list of open-ended and close-ended questions. Using this type of structure allowed the researcher to adjust to individuals' responses and hesitations in the moment. Further, this yielded additional questions used for subsequent interviews. Thus, the nature of the questions was participant driven.

Additionally, researchers used audio-recorders to document Skype interviews for thoroughness of data and the ability to reference information at later dates. No respondents declined to have answers recorded using audio-equipment.

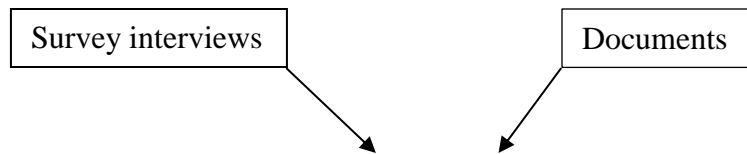
**Documents.** An additional data set was used to gather information in the form of documents. Since the events of the study began in the past, it was important to reference

documents and data sets that were pertinent to the study. Additionally, past accounts of situations were used to supplement the Skype interviews. Also, given the nature of the study statistical documents of mortality rates, population, percentages of women health care workers and previous study data were useful. Therefore, data from the Jhpiego, WHO, UN, and other sites was employed to substantiate the qualitative information gathered. Further, participants suggested additional literature and relevant materials.

The findings from the data collection were gathered and presented using a detailed description with quotes from respondents as well as interpretation within the framework of quantitative data analysis. Additionally the researchers own intellectual insights and original questions guided the narration of this study. The strength of the research is in its in-depth analysis of the phenomenon as well as its ability to fill in the gaps of exiting literature.

## **DATA ANALYSIS**

This section discusses the methods that were used by the researcher to analyze the data and provide a deeper understanding of community based interventions using a concurrent triangulation analysis of Afghanistan and a comparison analysis of other NGOs. These methods include data management, analysis and representation and are discussed below and were guided by the research questions (*Figure 4*).



1) What are the key determinants of successful community-based programs?

2) What are the lessons learned from previous studies?

3) What are the challenges and barriers to successful scale up? How can these challenges and barriers be addressed?

4) How can scale up efforts be integrated into existing health care systems?

*Figure 4.* Research Questions. Multiple sources of data used to answer research questions.

**Data management and analysis.** The researcher used data analysis procedures as recommended by Creswell for a case study. The first step was to gather the data and organize it into files according to categories. For this step Creswell (2009) recommends organizing the participants by letters and codes for easier retrieval and analysis. In order to determine the codes or themes, the researcher reviewed the data collected until patterns emerged and a system could be derived. Accordingly, these categories were applied to the research questions. Finally, the categories were developed into a code map so that the results could be easily identified and applied to the quantitative data. All responses were

conveyed without acknowledgement to protect the confidentiality of the interviewees. Because there is no easy way to validate qualitative findings, this study applied quantitative analysis to support the qualitative hypothesis drawn: that community-based advocacy and awareness programs should be used to expand the reach of misoprostol to treat PPH indications in the absence of skilled intervention.

**Quantitative analysis.** The researcher used the patterns of information obtained from the qualitative data to determine what quantitative data to employ from the documents. In addition, the results were matched with the research questions to identify whether or not the results supported the hypothesis that is expected. Further, the researcher provided insight or an explanation for the results. According to Creswell (2009), this explanation may include the initial theory for the proposed study, past literature or “logical reasoning” (Creswell, 2009; 153). Finally, the implications of the results were discussed as they related to future policy suggestions for the use of misoprostol and community based interventions in health systems.

## Chapter 4

### RESULTS

In order to appreciate and apply the lessons learned from pilot and introductory studies for future scale up it is imperative to root the discussion in a foundational understanding of both processes and outcomes. This foundation should seek to understand how the intervention was implemented and what steps were taken to achieve evidence-based results (WHO & ExpandNet, 2011, pg 7). Proceeding without saturated evidence can lead to unsustainable scale up efforts or may thwart future work with the intervention. As such, the following discussion presents the qualitative findings obtained from interviews with key personnel selected for their knowledge of misoprostol studies and safe motherhood practices. Quantitative data is added to support interviewee statements where applicable. It is worth noting that all of the individuals interviewed have extensive knowledge of misoprostol studies and have been working on projects to promote safe motherhood between 8-15 years in various countries.

Respondents were asked about their knowledge of current misoprostol studies for PPH prevention and treatment. In particular the first section covers questions interviewees were asked about how misoprostol was introduced within the community, as well as information on research outcomes, costs, financing, drug procurement, monitoring mechanisms, human resources, incentive structures, supervision, training and what changes, if any, they would suggest during gradual expansion of these programs. The second section identifies the barriers and suggested strategies respondents provided to overcome barriers involved with community based programs in general and with

misoprostol specifically. Finally, the third section discusses the interviewees responses to questions regarding the lessons learned from their involvement in these studies. In particular, respondents identified best practices for expansion of community-based interventions and how lessons might be applied to future work. Below are the key findings from questions as well as direct quotes from interviewees.

## **PROCESSES AND OUTCOMES: UNDERSTANDING IMPLEMENTATION STRATEGIES**

Misoprostol was introduced through a community-based, multi-tiered method in which key stakeholders from global, national and local levels were approached with evidence based research and a compelling needs argument. Participatory approaches which involve key stakeholders from the onset in the planning and implementation processes are more likely to scale up than those approaches that solicit little input (WHO, ExpandNet, 2011. Pg.3). One respondent indicated that:

Misoprostol was introduced through two ways in Afghanistan, through community sensitization meetings with leaders, of the Arabic religious leaders and health shuras and community members to explain what it was and what the program was doing and then also the community health workers. There were meetings conducted with the district health officials and provincial health officials and officials at the national level within the ministry of public health to help educate. So it was a multi-tiered approach.

Importance of community involvement was reiterated by every respondent. One interviewee remembered “We conducted formative research to know the practice and knowledge of the community on labor and delivery. Based on that research we developed our educational materials on misoprostol and then we introduced misoprostol into the community.” Respondents confirmed that involving various stakeholders from all levels

with particular focus on the community was imperative to project success. They also spoke about some of the logistics involved.

**Cost.** During the pilot project in Afghanistan all respondents mentioned that “cost was not a factor” because “misoprostol is not expensive.” And in their study in Afghanistan they looked at the cost “as if they [misoprostol] were procured in country” and asked the Ministry of Public Health if they “would be willing to do it for this amount,” roughly a dollar per dose. However, one respondent mentioned that this may not be true in every country stating: “Concurrently this inexpensive drug has become expensive in some countries.” As such, an important aspect of these programs is to include cost effectiveness analysis with scale up in mind from the outset.

**Drug procurement and financing.** Every respondent mentioned that misoprostol was supplied by NGO donations during the pilot project and that “We didn’t face any problem with obtaining misoprostol.” Many interviewees, however, expressed concern about what that implied for scale up efforts. Respondents stated that:

It’s one hundred percent depend [ent] on donor money. And if the day comes when we don’t have donor money then who will take this responsibility and provide misoprostol to the community. These are the type of challenges we should think about.

What I am finding is that countries often make commitments but then they don’t put a budget item for these things and then it doesn’t happen in these countries. Some of the worst countries... have a financial problem and there is no global mechanism to help poor countries get misoprostol, for example.

We continue to request funding from donors, which is becoming increasingly difficult, to continue work in PPH. Hopefully more countries will introduce it [misoprostol] into their maternal health program.

**Monitoring mechanisms.** Respondents carefully described the need for various monitoring mechanisms in terms of reporting and regulation and in terms of program



quality. Data on maternal mortality ratio, country or region specific PPH prevalence, rates of skilled birth attendance at birth, and results from PPH research and projects are important to provide decision-makers to assist in shaping policy. One respondent described how commitment among technical leaders through evidence provision at the national level helped champion program successes:

With advocacy and giving more information and presenting the data and evidence from best practices and evidence from other countries we were able to initiate the pilot program in Afghanistan. Once they [government officials, ministry of public health and other stakeholders] saw that this project was useful and feasible to implement in Afghanistan it was more acceptable to them.

Some of the reported results in Afghanistan included “verbal autopsies and maternal death audits in a household survey.” This information is important in the pilot phases as one respondent stated “Every program needs quality control assessments”. And “I think when you go to a scale up then you are moving more from the research type indicators to contact indicators.”

Smith et al., (2013) provides a review of global implementation experience to date involving misoprostol for postpartum hemorrhage prevention at home birth. Select indicators and results are provided in subsequent sections. Table 4 demonstrates the reported adverse outcomes for the programs included in Smith’s et al., global review. In the 18 programs reviewed there were a total of 51 maternal deaths with 24 associated with PPH (Smith et al., 2013). Yet, in the nearly 12,000 women who took misoprostol there were zero cases of maternal death attributed with misoprostol use (Smith et al., 2013). These results reaffirm the safety of misoprostol.

Table 4

### Adverse Outcomes

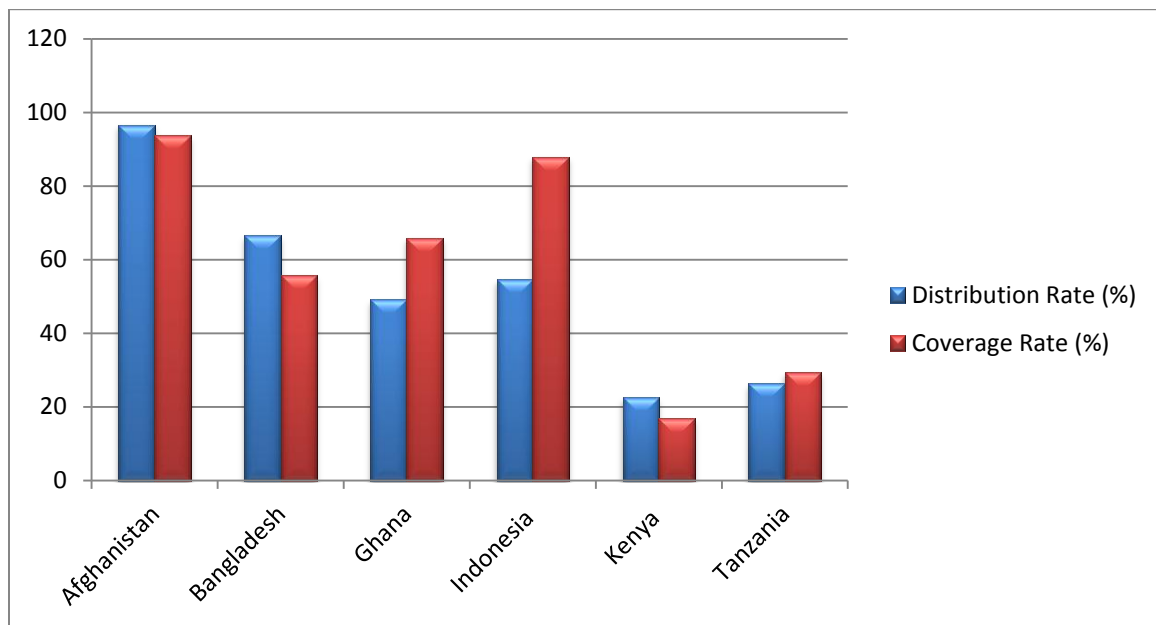
Outcomes	N of occurrences in programs reporting	Total # of women taking misoprostol at home births	Frequency
Administration before birth	7	12,615	0.06%
<b>Maternal deaths</b>			
Total	51	86,732	0.06%
Deaths due to PPH/excessive bleeding	24	86,732	0.03%
Perceived PPH/excessive bleeding	194	72,534	0.3%
Other adverse outcomes requiring hospital referral	27	86,732	0.03%

Adapted From: Smith *et al.* *BMC Pregnancy and Childbirth* 2013 **13**:44

doi:10.1186/1471-2393-13-44

In addition, although the data was limited, the projects included in the study supported national health priorities by demonstrating an increase in facility births (Smith et al., 2013). In Afghanistan, comparison between the control and intervention area demonstrated a 3.3% increase in facility birth rates (Smith et al., 2013). The most common delivery method was self-administration by the woman or with a TBA immediately following delivery of the baby (Smith et al., 2013). According to Smith et al., “programs that used these administration methods achieved both higher distribution and coverage rates, and rate ranges, than those which required skilled or trained birth attendants for administration (Smith et al., 2013). Qualitative information obtained also indicated that these projects were empowering to both women and health providers, as women came to learn that they could prevent PPH and promote safe delivery and maternal health (Smith et al., 2013). These programs enable greater coverage for the

prevention of hemorrhage (Smith et al., 2013). *Figure 5* demonstrates the effectiveness of programs through consumption or coverage rates.



*Figure 5. Misoprostol distribution and coverage rates (for selected programs)*

Adapted from: Smith *et al. BMC Pregnancy and Childbirth* 2013 13:44

doi:10.1186/1471-2393-13-44

Coverage rates reflect program effectiveness better than distribution rates because they demonstrate “both successful distribution as well as effective counselling to the woman, her family, and any involved providers” (Smith et al., 2013).

Significant to these findings is the observation that among programs using community-based workers to distribute misoprostol, there was a considerable difference in coverage rates. Nearly double the coverage rate occurred in programs with community-based distribution compared to those using health workers or ANC services (Smith et al., 2013). According to Smith et al., this may suggest that CHWs can add distribution of misoprostol more readily to the services already provided and may have

more opportunities to see a woman. In addition, the higher rates achieved may reflect that community-based distribution is not dependent on women seeking health care at a facility. Rather, the services are brought to them, where they are delivering. A few respondents highlighted that program success largely resulted from employing a “doorstep delivery of services” and that there is great need to bring the intervention directly to where women are giving birth. Overall the study concluded that high distribution and use of the medicine can be achieved through community-based programs for prevention of PPH at home birth employing diverse strategies (Smith et al., 2013). Smith et al., also concluded that higher coverage was achieved when misoprostol was “distributed by community health agents at home visits” and that “programs appear to be safe.”

**Human resources: incentive structures, supervision and training.** Additional considerations taken from the introduction of misoprostol include aspects of human resources including incentive structures, supervision, and training. Since lay health workers are volunteers it is important to conceive effective incentive structures to keep them motivated and prevent drop out. Many respondents spoke about the need for sustainable incentives. In particular, one interviewee stated:

The CHWs are volunteers and we need to provide them something to encourage them to do this work for the government and if it’s not a salary we should encourage them by some inclines [incentives] some mode of encouragement that they should continue this work for the government.

One of the challenges mentioned by respondents during the pilot projects was “the drop out of CHWs.” Further, the MoPH cannot afford to pay the CHW’s a salary because currently there are “over 2200 in Afghanistan and even a small salary per CHW would be

a huge cost” and “burden on the health care system.” As such the “ability of the MoPH to motivate the CHW’s and to find a way to keep them motivated is critical” as one respondent stated.

Equally important is the need to make sure “that the community health workers who are doing this are supervised.” The community health workers were selected by community leaders and members. As one respondent reiterated, “this is not about just taking anybody in the community and letting them go out and do it. There is a process behind it.” Fundamental to program success is integrating these CHWs into the national system and to ensure that they “are using the system support” that they are “sufficiently trained” and “connected to a formal health care facility where they receive the medication, where they receive re-education and re-motivation and that the community health worker then becomes an extended part of the formal health care system.” Every respondent agreed that the training should be “community-based for CHWs” and “monitored by health supervisors” as the “key for quality of the training.” Respondents focused on “ensuring quality of training” because “the training is the key component to the implementation.” And as the program is scaled up, maintaining quality training and supervision, according to interviewees are critical components of program success.

Every respondent indicated that the approach taken to introduce misoprostol into the community during the pilot projects that they participated in or had firsthand knowledge of was “the right one” and that community acceptance of these approaches was high. Specifically respondents said:

It was hugely acceptable by people, by community and by community leaders because we spent a lot of time on advocacy. Most of the communities around the facilities are very interested to have the project in their communities.

The accounts I heard anecdotally were all very positive about misoprostol. We heard stories of people being very appreciative because maternal mortality in both Afghanistan and South Sudan is a major cause of mortality.

If they get pregnant they will use it [misoprostol] again and that showed us that it's acceptable by the community.

While respondents did not indicate needed changes to how misoprostol was introduced within the community during the pilot programs they were involved with, there was a consistent message that these tactics and best practices should be replicated in future programs. Specifically, respondents spoke to the need to involve the community early on and to understand the local context. One respondent says “if they want a successful project they need to go to the community and ask them to join you. Ask them [community] to decide this is the most important decision....” And, before a community based program can go national you need to have a “smaller introductory phase” in which policies, customs, and norms are taken into consideration. Once you have “gained confidence” from the community, government, and other political parties you may scale it up. Many interviewees acknowledged the importance of controlling the intervention during these processes because “you don’t want things to go wrong.” Additional key determinants of successful programs and lessons learned are discussed in the following sections.

## **KEY DETERMINANTS OF SUCCESSFUL PROGRAMS, BARRIERS, SUGGESTED STRATEGIES TO OVERCOME BARRIERS.**

International agencies and governments seeking to expand effective pilot models to national scale often reach out to Jhpiego (Jhpiego, 2013). As such, key informants from Jhpiego and other agencies were asked about the crucial determinants of successful community-based outreach and advocacy programs, potential barriers and challenges, and suggestions for overcoming these challenges. Interviewees provided insight into the factors that yield a successful community based outreach program based on their extensive research and participation in pilot projects across countries such as South Sudan, Nepal, Indonesia, Bangladesh, and Afghanistan.

**Key determinants of successful programs.** There was a resounding consensus among respondents that the key to a successful program relies on the strength of the advocacy, education, and delivery and monitoring mechanisms of the intervention implementation. Within the strategy, individuals reported a focus on sharing evidence with and involving key stakeholders and community members from the beginning, bringing the intervention to where women are delivering, and focusing on educational components of the intervention. In fact, many of them distinguished between the importance of distributing misoprostol and distributing educational interventions citing that “distribution of the drug is secondary to” the distribution of “the education.” Below are the direct quotes from interviewees regarding advocacy and education. Discussion around delivery and monitoring mechanisms has been included within the barriers piece.

***Advocate with evidence.*** Respondents all spoke about the importance of advocacy throughout the project in order to increase awareness, generate support, and maintain project goals. In particular respondents said:

The key is advocacy and the key is the stakeholders.

I think the most important part is advocacy. That's why we were successful in our project.

We engaged the community at the beginning of the project. We spoke to the community and said if we decide, we can work together and implement the project together. So it's the community's decision. Because of this approach, the communities were empowered.

In the future, to implement projects for the benefit of the community, the community decisions should be considered and involved right at the beginning of the project and not later, even before the project is started.

Based on our study and data, if we expand misoprostol and prevention of PPH in Afghanistan on a larger scale I think the right approach is to involve community leaders and community members in the project. This is the key for a successful project in Afghanistan.

***Educate for effective care delivery.*** Respondents all agreed that adapting the educational materials within the local context was important. They said you may have “a good intervention but you have to work within the context of the country.” One respondent gave particular details about how the community was involved in the process of program development and implementation. “We asked women, husbands, communities and community leaders, what do you want misoprostol to be called? Is it acceptable to you if we draw pictures like this to prevent PPH? Do you want CHW's to distribute misoprostol or someone else? How should CHWs teach and council you? And how do we empower CHWs?” In Afghanistan, misoprostol was called “tablets against PPH” in the local language. And “because it was their idea, the package was their idea;



the name was their idea” it was “very acceptable by the community.” Further, results were taken to the MoPH and other stakeholders to demonstrate that “if they want a successful project they need to go to the community and ask them to join” and “ask them to decide” what “is the most important” need so that they may “decide among themselves” and help contribute to the materials and program. In particular, respondents said:

For me the most important emphasis needs to be on the educational component.

Involving community from the start and advocating CHW education on PPH prevention is the key to a successful project.

You need to have community acceptance and a lot of education on how to use it, what to do, and what not to do.

You really absolutely need a bottom up approach in that regard. You have got to have alignment in the community in order to do this.

Most important is that women and their partners and their spouses and their support persons need to know about PPH and they need to know when exactly to take the tablets and when not to take the tablets.

We believed that education was more important than just the distribution. We made educational understanding of the message key to receiving the medication. If you remember the message correctly [about when to take misoprostol] then we are going to give you the medication. If you haven’t remembered correctly we will re-educate you until you can remember it, then you will get the medicine.

**Main barriers and challenges.** Understanding how pilot programs were implemented is important for future work. Uncovering best practices through knowledge of pitfalls and challenges faced are equally important. As such, the questionnaire asked respondents about the numerous barriers they faced and for insights into how to address these challenges. Reported barriers are listed below in order of perceived importance as

indicated by the frequency in which respondents mentioned each barrier. The most frequently listed barrier is listed first:

- Political<sup>1</sup> pressures
- Delivery mechanism controversy
- Product quality and safety
- Women's empowerment
- Funding
- Geographical and weather constraints

Descriptions of each barrier as well as suggested strategies by respondents for overcoming them are provided below.

<sup>1</sup>While respondents called these political pressures; they included sociocultural factors as well. The researcher refers to these pressures throughout the results section as political to maintain consistency with the respondent's terminology.

***Political pressures.*** The most frequently mentioned barrier involved a wide range of political issues regarding: misoprostol's association with abortion, fear that women could harm themselves if misoprostol is taken incorrectly, perception that misoprostol would lower facility birth rates, and the impact that adding misoprostol to the essential drug list could have on pharmaceutical companies' business and other outcomes. Respondents were careful to distinguish that while misoprostol may be used for abortion or incorrectly by women, that these may not be the genuine obstacles for government and WHO hesitation to add misoprostol to the essential drug list. Rather, it was stated that adding misoprostol to the essential drug list and including it in the safe delivery kits may adversely impact pharmaceutical companies' business. As one respondent indicated "they know the benefit of misoprostol" and present the "misuse as an excuse" to not put misoprostol "on the essential drug list" when in reality "they are worried about their own

business.” Another respondent said that it was “too political” and WHO wanted to stay away from this issue because of the “politics involved.” This view may not be representative of all cases of concern surrounding misoprostol and abortion. However, it is worth noting that every respondent interviewed highlighted the political barriers faced in adding misoprostol to the essential drug list and provided compelling arguments to overcome both associations with abortion and safety concerns. The following quotes provide insight into this topic.

*Fears of misuse of misoprostol.*

A major obstacle that we have is the mindset of the stakeholders at a higher level. They are afraid of misuse of the drug. However, when you go to the community we don’t have any problems with that. It’s hugely acceptable. Yet, when you talk to the health stakeholders, including those involved with the essential drug list or the drug department or even at the higher levels they are all afraid of the misuse of the drug. They are concerned that this medication will be misused by people for abortion purposes and there are some concerns about the safety of this drug. Clearly if this medicine is taken before the birth of the baby it can potentially be dangerous.

The government thinks that if we distribute misoprostol widely then it will be misused by the community. For example, women will use it for abortion or they will misuse it for another purpose.

There is a lot of political pressure not to allow women to use it [misoprostol] because this drug *can* be used for abortion.

*Reluctance to take action.*

From a politician standpoint, they talk about maternal mortality but when it comes time to take action they cave in on certain issues.

There is a risk and concern from professionals who are unwilling to give up this task shifting issues.

*Hesitation from WHO and governments to add misoprostol to the essential drug list.*

We struggled almost over a decade with WHO to include misoprostol on the essential drug list. The fight is never over. Right now if you go to the world health organization's website you will see people asking for the removal of misoprostol from the essential drug list.

WHO does not want to be in the front line and say everybody should use misoprostol through community based approaches to prevent PPH and save lives. They have never attended a single advocacy meeting in terms of misoprostol use at the community level and they have never been involved in any forum or discussion in this regard.

This is a very political decision for government and they don't want to be that involved in political things.

*Adverse impact on business.*

There is a lot of political pressure; they don't want to have this on the essential drug lists because a lot of pharmaceutical companies and doctors receive a benefit from these medicines. And now if we add it [misoprostol] to the essential drug list and distribute it freely to the community than those markets, pharmaceutical companies, and doctors will be affected.

We have a pharmaceutical committee based in the ministry of public health and another larger one, independent from the ministry; they are the most resistant groups because their concern is their own market and their own businesses.

*Concerns about decreasing facility births.*

There is some concern that if women think that they are protected at home than they will not seek skilled care.

Most communities don't want to touch health care issues working in the community because there is a sense that if you work in the community women will never come to the hospital.

There is perception that if you allow women to have an intervention to help deliver at home that that will deter all the efforts that are out there to increase facility births. That is totally wrong. We were able to disprove this with the misoprostol intervention.

We are confident that just because people have a means of protecting themselves that will not mean necessarily that they will not want to go to a skilled provider.

In response to the political pressures mentioned, respondents spoke about advocacy with key stakeholders, educational messages, and refining market approaches to reduce the negative impact on pharmaceutical companies. With regards to the association with abortion, the respondents indicated that “there is no work around because it *can* be used for abortion.” What could be accomplished is monitoring the misoprostol packages, emphasizing how misoprostol can save lives and how misoprostol might make abortion safer. Here are some of their direct quotes:

***Suggestions for overcoming barriers: political pressures.***

*Association with abortion; how misoprostol might make abortion safer.*

Some people are going to use it for abortion and have been using it for abortion. But that is a different problem that needs to be addressed with a different solution. Taking away the ability of women who are going to deliver a baby to protect them against PPH, which is the leading cause of maternal mortality, is not the way to do it. It’s an unfair way to take away the ability to save lives, just because you don’t want them to use it for something else, for abortion.

Women will try to interrupt pregnancies wherever they are and they have been doing this before misoprostol. It’s not going to go away but you might make it [abortion] safer. By having misoprostol distribution you do not reduce the number of abortions, but you might make it safer because they are not going to be using coat hangers and other things.

*Tracking the packages, timing, and dosage.*

We want to make sure that misoprostol cannot be leaked out from the community and that is why we made a package with a serial number. This allowed us to track the unused packets of misoprostol in the community.

We actually retrieve all of the medicine that is not used, so there is not all that much medicine hanging around.

We have to prevent the misuse for abortion in those countries where that [fear of misuse] is an issue by only distributing misoprostol [to women] around 8 months.

The woman only has one dose of misoprostol so misuse for abortion is not a big issue.

The government and ministry of health need to establish a strong monitoring system in terms of pharmaceutical companies, markets, and distribution mechanisms. These types of monitoring systems can ensure that misoprostol is not misused at the community level.

*Advocacy with stakeholders.*

I think for political pressure we need lots of advocacy with key stakeholders. For example, the ministry should recognize this is the best approach to decrease maternal mortality in this country[Afghanistan] and get buy-in from others who are resistant to this approach. Parliament members would be another solution; they can go and talk to people who are resistant and convince them that they should approve this approach and that we should distribute this medicine at the community level.

*Overcoming perceptions about facility birth rates.*

Our society has developed over the years by thinking that health problems are mostly solved in health facilities. I don't accept that notion. I think that health problems can be solved at a variety of components of the continuum of care. So I am a true believer in the continuum of care starting with things that can be done given the conditions of the community.

Well I think that we have tested in so many countries right now that the perception that misoprostol will decrease facility births is sort of not there anymore and realization that some women will not be able to reach facility is more clear to everybody.

We have actually seen an increase in the use of skilled attendants not a decrease because people now understand why they need to go to a skilled provider.

*Educational messages.*

We increase the safety from the educational program not just the distribution program.

We have demonstrated in our studies because we have presented this medicine as Plan B that if a skilled provider is not there then you use this medicine. If a skilled provider is there, then let the skilled provider use oxytocin or whatever she's got.

With every country people need to understand the quality of the program and its effectiveness. You need the message that this is an educational intervention.

The community should be aware of the side effects and risks of this medicine if they want to use it for prevention of PPH. They need to know how to use misoprostol.

If the community wants to use misoprostol for other purposes, they need to know the danger of using misoprostol for these purposes.

*Refining market approaches.*

If we change this approach in the way that their market [pharmaceutical companies] shouldn't be affected than I think we can get their buy-in earlier.

Coordination with pharmaceutical companies and sellers who are directly giving the medicines to the community would be a good solution.

***Delivery mechanism controversy.*** Most respondents also mentioned concerns over who can provide misoprostol at the community level were a barrier. Many characterized the debate as falling into one of two “camps.” One respondent indicated, “the community based distribution element” is the “aspect that has been growing more polarized in terms of how people see it.” Some feel there is “enough evidence showing that community health workers distributing misoprostol at the community level is safe, acceptable, feasible,” and “can be done effectively.” Yet others believe it should be done by “skilled” providers. One respondent stated that:

There is controversy around the idea to distribute misoprostol by community health care workers because they do not know the exact side effects of misoprostol and they are afraid that the CHW may guide the community in the wrong way in which to use this medicine or that the community may face the risk of misuse of this medicine.

The WHO has called for more evidence in this area. One respondent indicated that the WHO sees the results from pilot studies and says “the project is too small” and the “sample” is “not big enough” to say that “the use of community health workers to distribute misoprostol is safe.” In addition, some argue that the level of education of the CHW's is not “high enough” and that they should not “involve people who are not well educated in these processes.” Ultimately respondents agreed that “in terms of distribution, the goal is to reach women where they really are.” And understanding “how

you get maximum coverage in the most efficient and safest way” is one of the most important factors. According to respondents there has been enough evidence generated to demonstrate that misoprostol “is a very safe drug” and what matters “is that every woman that doesn’t deliver in a health facility and doesn’t have access to a hospital setting should be taking misoprostol.”

***Suggestions for overcoming barriers: delivery mechanism controversy.***

*Mass communication.*

Everybody should know what the drug is for and how to take it to minimize the risk that the drug is taken in a way to bring adverse effects.

We learned that it is not difficult to establish channels for distribution at the community level. And that through open discussion with the community we were able to find solutions, local solutions.

*Training and stakeholder involvement.*

The involvement of all stakeholders even if they don’t distribute the drug is important.

If a woman is delivering with a TBA we need to find ways to involve them as part of the support group. The TBA needs to know what the drug is about and why the woman is taking it so that they can be on our side rather than fighting against us.

The government needs to take the lead with the support of local NGO’s and private sector in monitoring, investing in training, community awareness, and especially in the distribution of misoprostol.

*Inclusion of misoprostol into the existing training programs and safe delivery kits.*

They [governments] need to change policy to make the drug available and have it in safe delivery kits.

Some countries distribute misoprostol alone and some use the safe delivery kit like Ethiopia and Bangladesh. Countries need policies that allow such distribution. The distribution of misoprostol by CHWs is not part of the curriculum. Currently it is just about misoprostol and the benefits and risk of misuse. This curriculum did not address how a CHW could distribute this medicine. We are trying to advocate that some materials



and information be included in the curriculum about distributing misoprostol through CHWs and how to train women to use this medicine.

The most important thing is to include it [misoprostol] in the essential drug list and basic package of health services to make sure these medicines are easily available for community based distribution.

Training materials exist for different levels of cadre in the health care system, including for the women themselves who use misoprostol. If we include misoprostol in the health extension worker package like we did in Ethiopia, within two years most of the village was using the health package.

We are still at the beginning of our approaches and it is a good time to think about how we can make the distribution mechanism and community-based approach more sustainable.

I think it is the right time to think about the family health action groups as a way to distribute misoprostol when CHW's are not available. These groups can add misoprostol to their program.

***Product quality.*** Two-thirds of respondents mentioned various product issues as barriers. These included drug registration, quality, and supply chain problems. The following quotes provide additional details regarding these points.

*Quality.*

Right now one of the big problems we are facing is about half the misoprostol that is in the world is of poor quality.

There have been concerns about quality of the drugs. That is something that needs to be addressed

*Registration.*

Misoprostol needs to be registered by a drug regulatory agency. Otherwise you can only import with authorization from the ministry of health for specific studies.

Food and drug authority registration in each country is important so you can import it [misoprostol] and so it can be used in programs.

*Supply Chain.*

Most of this drug [misoprostol] comes from India, Bangladesh, and China.

One of the main challenges with distribution is the importation of misoprostol since we had to have it donated. The timeline of doing that was a challenge.

*Suggestions for overcoming barriers: product quality.*

*Registration.*

First of all the drug needs to be registered in the country.

*Verify quality.*

You need to make sure that the ones [misoprostol tablets] that are in the community programs are of good quality. So you have to buy good product.

I wish we had paid a lot more attention to that [product quality] and done some prequalification's of the companies that are producing it. That is being done right now.

*Involve stakeholders.*

Everyone can participate in terms of public and private sectors. Can and should participate!

NGO's that work in the community of maternal health should be helping the government with access. UN agencies like United Nations Children's Fund (UNICEF) helps with drug procurement, and OBGYN commission for quality of misoprostol. All of these parties should participate.

*Inclusion on the essential drug list and within national health programs.*

Countries need to introduce misoprostol into their maternal health programs.

Misoprostol is available in country but if it is on the essential drug list and it is used at the national level within the health system then there will not be an issue in terms of importation.

The consensus is that if misoprostol is registered for PPH and is made available through the private sector that these steps may help navigate the reluctance of manufacturers to label misoprostol for uterotonic indications (Coeytaux & Wells, 2011).

Respondents indicated the need to be more careful with product procurement to ensure quality. One respondent also mentioned the need to understand more about product expiration dates and how current distribution methods might be impacted by expiry. Ultimately, product quality needs to be improved. According to a couple of respondents this is currently being addressed.

***Women's empowerment.*** A couple of respondents identified the lack of focus on women's health issues and gender as a barrier to the use of misoprostol for PPH prevention and treatment. They highlighted the fact that many women are not able to reach facilities because of gender or sociocultural influences and the continued low status of women. Providing misoprostol and bringing the continuum of care to women where they are delivering is empowering. Respondents' comments about gender and empowerment are below:

*Compelling need to save lives.*

People need to understand that it is wrong morally, ethically, professionally, and politically not to help women who are having births at home.

We cannot blame women for having births at home. We cannot marginalize women who have births at home. Those women may be challenged by finances. Those women may be challenged by geography. Those women may be challenged by culture and traditional things. That does not mean they do not deserve to be protected from PPH and other issues. We just have to find better ways of doing it.

We need to make the case that women's lives are worth saving.

There is more focus on child survival than on maternal survival because I think they love babies more than mothers and that is a bit sad.

*Empowering Women.*

It gives the woman some ability to control what is going to happen. One thing they do not have control over, for example, is whether they can reach a skilled provider in time or whether a skilled provider will reach them in time. They don't have control over that.

They don't have control over a lot of things. But at least for this particular condition [PPH], they could take the medicines to protect themselves. I think that is very empowering to women.

There is always someone in the community who has experienced bleeding and there are also a lot of near misses or instances when the woman almost died. To know that you have this drug and these three tablets that can prevent bleeding from occurring and therefore you might save a life is empowering. Even in a place like Afghanistan and Northern Nigeria, in the very traditional part of the communities, we had great acceptance including men.

They need to understand that this program is about empowering women because that is what it does. It helps them save their own lives

***Suggestions for overcoming barriers: gender and empowerment.***

*Bring the intervention to where women are delivering.*

They were very eager to find solutions and I think a recognition that if the solution could only reach people in the facilities than we would clearly never manage 50-60 percent PPH mortality from happening. There is recognition that an intervention was needed wherever women were giving birth and it was very important in those three countries [Nepal, Indonesia, and Afghanistan] for the adoption [of misoprostol].

It is important that studies in place to decrease PPH have to be devised to include all women wherever they deliver. And then you tailor the intervention according to the local context.

The goal is reaching women where they are with the drug.

*Educate women and family members as providers of their own care.*

The one person, who is always going to be present at birth, is going to be the woman herself, so she should be keeping the medicine that is there to protect her.

We sent a lay community health care worker and trained them in a way that they could talk in the same language as community members and tell them that this medicine is for

your health and your benefit. The community is open minded and they want to improve their health situation

We showed the community that this training will benefit their own community it's not for anybody else. The benefit will come directly to your own community.

*Funding and cost effectiveness.* Two respondents spoke about the lack of resources and funding needed to continue reproductive health work.

If a nation truly believes that a woman's life is worth saving, then that nation will invest in saving the lives of women. I have a feeling that in some nations either they don't have the money or they have not made that commitment sufficiently enough to put money into that.

We continue to request funding from donors, which is becoming increasingly difficult, to continue work in PPH.

The other lesson we learned in a negative way is that we are very donor dependent. These tablets are purchased by some donor organization. Currently donors are supporting us, if we scale up this project they promise to support us and that they will provide us with as much supply as we want. But after what time will they stop supplying us, after one year, two years, three years or ten years. What will happen after that? These are the things which we should think about and how to sustain it.

And in terms of cost effectiveness we should provide some data to the government to prove that misoprostol will be more cost effective than if a woman faces PPH and then comes to the health facility and the doctors have to perform a lot of other interventions. Instead with the three tablets, and with the lower cost, you can survive.

I think it is still a big question mark how to sustain a program which is run 100 percent with donor's money.

We are unsure of the sustainability of this approach [using donor money] and do not know the cost effectiveness.

In Afghanistan where the NGO's are still being contracted by the ministry of health to deliver the health services then it's the training aspect and it's the cost of supervision and monitoring as well that need to be thought through.

***Suggestions for overcoming barriers: funding and cost effectiveness.***

***Gain support from the community.***

We can ask for contribution of communities to contribute and pay a small amount of money when they are receiving the tablets.

First we need to work on the community awareness about this medicine and benefits of medicine and risks of those medicines and then we can convince them to buy those medicines for themselves if they need it. Then we are more independent from donor money.

In the future we should count on the involvement of the private sector that can help us with the cost of misoprostol.

***Geographical and weather constraints.*** Two respondents spoke about additional barriers reaching women because of geographic constraints. One respondent stated that “Afghanistan is a mountainous country and some areas of the country and roads are closed in winter. So people have no access to those communities.” Another respondent mentioned that “women may be challenged by geographical” constraints. And they acknowledged that “In one health facility we failed to ensure they had enough for winter because it was very difficult to reach them.” In order to overcome these barriers, one respondent suggested that program implementers plan ahead for these types of issues. Specifically they stated, “We have to be aware and make a plan to reach those communities while the roads are open. We need to make sure we have enough supply before the roads are closed by snow.”

**LESSONS LEARNED FOR SCALE-UP**

The ultimate aim of this project is to understand best practices for expansion of community based interventions. In particular, the outcomes and lessons learned from

gradual expansion of these programs and how they may be applied to other countries and additional expansion efforts regarding misoprostol distribution to prevent PPH at home births. Respondents were asked to share their thoughts on how to best integrate training directives for misoprostol dissemination, dosage and usage into existing health care training and safe motherhood structures. They were also asked to discuss how these programs can be tailored to fit local contexts and be sustained to continue monitoring objectives. Finally, they were asked to share suggestions for expansion of community-based interventions and future work with misoprostol. These lessons have been summarized in Table 5.

Table 5

*Collection of Lessons Learned from Key Informants and Documents Regarding Community-Based Interventions.*

Area of Topic	Lessons Learned
Research	<ul style="list-style-type: none"> <li>• Collect evidence and share data with stakeholders. Research data is extremely helpful in influencing key stakeholders to support program goals and garnish action for scale up efforts.</li> <li>• Additional pilot programs more characteristic of the scaling up setting may be needed. For example, in Afghanistan they may need to pilot a program in a more conservative area.</li> <li>• Use regional expertise to ensure relevancy and ensure regional support.</li> <li>• Additional studies on multiple doses, product quality, and cost analysis may be needed to understand scale-up implications.</li> </ul>
Evaluate Intervention	<ul style="list-style-type: none"> <li>• Ensure the intervention is relevant to national needs.</li> <li>• Evaluate complexity; the intervention complexity should match the capacity of the implementing organization or capacity-strengthening should be part of the project.</li> </ul>

	<ul style="list-style-type: none"> <li>• Review priorities, needs and capacity before determining intervention processes.</li> <li>• Review key documents including current reproductive health strategies, basic package of health services, and basic package of hospital services to identify national priorities and to ensure the intervention is consistent with those priorities.</li> <li>• Perform a task analysis to understand current functions of health workers and whether the intervention may be integrated into their competencies and activities.</li> <li>• Advocate for the importance of the innovation in areas where its relevance is not widely accepted. For example, because misoprostol has multiple indications, advocacy is needed to provide transparency around these various uses.</li> </ul>
Advocacy	<ul style="list-style-type: none"> <li>• Determine who relevant stakeholders are and ensure representation from those who influence policy including community members and leaders, ministers, council registrars and professional association leaders.</li> <li>• Engage stakeholders in planning, implementation, and problem-solving processes. Conduct meetings with stakeholders to generate consensus and support.</li> <li>• Identify champions who can advocate for PPH interventions at various levels: local, national, global.</li> <li>• Engage stakeholders in dialogues surrounding needs argument, existing practices, policies and training curriculum to understand current PPH prevention and treatment methods</li> <li>• Participate in local and national meetings to create awareness and help stakeholders understand factors involved for PPH prevention.</li> </ul>
Education	<ul style="list-style-type: none"> <li>• Tailor the intervention to meet the local sociocultural context</li> <li>• Identify potential constraints such as community, gender, religious or other sociocultural factors that may bolster or thwart implementation.</li> <li>• Analyze political, health-sector, government and other institutional norms that may influence scale up processes</li> <li>• Discuss the intervention with donors, global agencies, educational institutions, government, political professionals, NGO's, and maternal health organizations</li> </ul>



	<p>to generate support.</p> <ul style="list-style-type: none"> <li>• Host individual and group meetings and use print media, radio messaging or other social media to educate women and families about the purpose and proper use of misoprostol, dangers of PPH, and importance of skilled attendance at birth. (Programs which emphasized these messages supported government health initiatives and saw increased facility birth rates according to Smith et al., 2013).</li> <li>• Incorporate intervention into pre-service education and provide in-service training for all levels of cadre of health care system.</li> </ul>
Training/Supervision	<ul style="list-style-type: none"> <li>• Ensure training materials exist for different levels of cadre of health care system, including for the women themselves to use. (“We have pictorials and words to capture those who can read and those who cannot.”)</li> <li>• Focus training on the lower levels like TBA’s, community health workers, health technician workers who have the most access to women where they are giving birth.</li> <li>• Ensure training materials include misoprostol for PPH and community based distribution methods.</li> <li>• Each country should develop its own strategy for recruitment, deployment, and retention of health workers (WHO, 2010).</li> <li>• Provide opportunities to ensure workers and supervisors maintain clinical expertise, understand new protocols, and have access to resources needed to provide support with the intervention.</li> </ul>
Monitoring Mechanism	<ul style="list-style-type: none"> <li>• Document key quality indicators and be prepared to adjust indicators as the intervention moves to scale</li> <li>• Develop a plan to capture program process, outcomes and lessons learned. Knowing what is effective when implementing educational interventions is critical for scaling up and informing other programs (USAID, 2011).</li> <li>• Monitor packaging/tracking to ensure no opportunity for misuse.</li> <li>• Involve stakeholders and government in monitoring requirements for scale-up.</li> </ul>

Financing for  
Sustainability and Scale-  
Up

- Strengthening existing and establishing new financial donors is imperative to scale-up and should be considered early on (USAID, 2011).
- Involve stakeholders in financing needs for scale-up to help mobilize additional resources and political and government support.
- Improve capacity of government and institution to increase ability to sustain program.
- Engage in cost effectiveness analysis to understand

linkage between macro-level funding mechanisms and adequate budgetary allocation.

Distribution

- Need to add misoprostol to essential medicines list to allow for distribution mechanisms (part of safe delivery kits)
- Determine who is able to distribute misoprostol. (“Some countries CHWs may not be allowed from a policy perspective to distribute drugs and you may find that in some areas in the country there are no CHWs”)
- Bring intervention and emergency obstetric care as close to the family as possible through community health workers and providers.
- Social media can be used to distribute educational messages about the intervention.

Sources: Some information obtained directly from respondents during the interviews and from supporting documents.

Respondents indicated that the foundation has been laid and that it is the right time to expand community based distribution of misoprostol. One respondent said:

It is the right time to start preventing PPH in the world where people don't have access to skilled birth attendance. There is more than enough data to support CHW distribution of misoprostol within the community, not only from Afghanistan's project but through other studies and lots of other countries in Africa and Asia. There is enough evidence that 600mg is effective.

Another respondent's recommendation was not to "reinvent the wheel." There are enough completed projects and piloted studies that you can "take the ones that have been done before" and learn from them. Further, it is "not rocket science." Rather organizations "just need money and commitment" to do this type of work "on a very large scale." What would help propel efforts is if "we include misoprostol in the health extension worker package" or if the government would add "misoprostol to the essential drugs list and Basic Package of Health Services" and ensures "that these medicines are easily available for community-based distribution." One respondent indicated that "every country has to do this in a stepwise manner." Once "people gain confidence", as they would with "the introduction of any new intervention," and you have "figured out many of the oppressional [sic] issues through a smaller introductory phase," and "worked within the context of the country" then you may scale it up. Overall the main lessons and themes gathered from the respondents are listed below.

- The key is advocacy and stakeholder involvement.
- Integrate the intervention into existing health programs whenever possible.
- Funding needs to be shifted from NGO's to governments and local organizations responsibility for scale up in order to be sustainable.
- Maintain quality within training programs and product as the intervention moves to scale.

Overwhelmingly, respondents said that despite the barriers they encountered that there are very few changes they would make to how the pilot programs that they worked

on were implemented. All respondents agreed that there has been enough evidence to support expansion of community based distribution of misoprostol for the prevention of PPH at home births.

## Chapter 5

### CONCLUSIONS

Many people in developing countries have limited access to health technologies, services and community-based interventions that result in unneeded high rates of mortality. Relevant research and pilot programs have been implemented to address these deficiencies. The knowledge and expertise exists, but the lessons learned and best practices for scaling up these programs are not always readily available to those who require them. As such, this project looked to examine the work of community-based programs working to expand the reach of misoprostol for PPH at home births. In particular, the project sought to understand how programs have been implemented in the past, the key determinants of their success, the barriers and pitfalls encountered, lessons learned and the application of this knowledge for scaling up community based implementation programs and policies that fit the individual contexts of countries and localities.

Given the growing body of literature and studies surrounding the use of misoprostol for multiple indications within reproductive health care and neophyte efforts to expand misoprostol's reach, this project was extremely timely. After extensive review of the literature together with case study analysis of the misoprostol work accomplished by Jhpiego in Afghanistan and interviews with key personnel, this project concludes that broader expansion of misoprostol is feasible and safe. It isn't a question of whether or not misoprostol is ready for expansion, but whether governments, health officials, and politicians are ready to support expansion.

The respondents who participated in the questionnaire are clearly the industry experts on this topic who have laid the foundation for future work and expansion of not only the use of misoprostol but the community-based approach used to do so. Most were emphatic about the need to look at this work more in terms about the distribution of educational interventions rather than the distribution of a drug. There was consensus that this work can only move forward with continued advocacy, education, and training. Moving these components forward and overcoming barriers requires sustainable funding and strong supervisory and monitoring mechanisms.

Given the shortage of health care workers and barriers to receiving medical care within hospital settings this project suggests an expanded role for women in securing self-sustaining solutions to their health problems. In order to scale-up efforts alternative solutions need to be explored where women are empowered to administer misoprostol without skilled assistance and additional community driven programs are implemented. In order to advance these alternatives, perceived barriers to the use of misoprostol need to be addressed.

The interviews revealed that the largest perceived barrier to moving ahead with misoprostol expansion is politically based. There is widespread fear that misoprostol will be used for abortion or misused, causing harm to women. In addition, respondents discussed the political pressures surrounding adding misoprostol to the essential medicines list. In order to address these barriers there is a need for global consensus around evidence-based guidelines for the use of misoprostol for PPH indications. Given that misoprostol is already being recommended for PPH indications heightens the

urgency for evidence-based approaches. There is an opportunity to make a difference in the outcomes of maternal mortality and to save lives through misoprostol—one that does not depend on the strength of health care systems (Coeytaux & Wells, 2011). Advocacy groups need to adjust strategies for using misoprostol for PPH as evidence accumulates around best practices and safest approaches. In addition, the reproductive health community cannot hide the multiple indications of misoprostol, including its use for abortion. Local solutions need to be sought to address political implications for the use of misoprostol for abortion and international recognition for its multi-facet indications (Coeytaux & Wells, 2011). With better information about how misoprostol can be best used for each indication (labor induction, PPH prevention and treatment, post-abortion care, and abortion) common goals can be achieved: to save the lives of women.

To achieve substantial reductions in maternal mortality and risk, there is no substitute for skilled care, health facilities, and emergency obstetric care. Yet, gaining access to these services may not be possible. Misoprostol, therefore, serves as a complimentary service in the continuum of reproductive healthcare. However, the recommendation to expand misoprostol use and community-based interventions lies entwined within the comprehensive discussion of the lessons learned from previous projects and commentary from interviewees.

Lessons from this study can help direct public health practice in Afghanistan and in other countries. And while many have been listed, the following are a few of the most frequently discussed lessons learned by respondents. First, the project revealed that there may be a need for additional community-based projects in more conservative areas of

Afghanistan. Carrying out programs in a limited scale-up may validate that program performance can be maintained in more conservative areas using lay health workers or family action groups. In addition, focus should be placed on community behavioral change. Further focusing messages on how to safely use misoprostol, the risks associated with misuse, and the benefits of these medicines will help mediate political pressures. In the programs that focused on educational messages and enforced message memory, there were higher rates of facility births and understanding by women to involve skilled care during delivery (Smith et al., 2013). As such, implementing community awareness and behavioral change components could further increase expansion efforts by overcoming potential barriers.

Enhancing reproductive security and determining correct reproductive health BCC components relies on curbing the negative impacts of gender discrimination and empowering women. Community-based approaches must understand and address the dynamics of household decision-making by raising consciousness about reproductive health needs, helping women mobilize resources, and support grass-roots efforts and essential health service packages.

Finally, the project revealed that programs should concentrate on integrating the educational materials and intervention within the existing health care infrastructures whenever possible; training materials should be adapted to include the distribution of misoprostol by lay healthcare workers and address local context. This is the most effective way to achieve community-based implementation. Ultimately there is a need for additional studies on dosage, cost effectiveness, and drug quality in order to propel



community-based distribution of misoprostol. Some believe the evidence is saturated and that “it is the right time to start preventing PPH in the world where people don’t have access to skilled birth attendance.” All interviewees agreed that it is the right time to start saving lives. Misoprostol is readily available, low cost, and can easily reach women where they are delivering. It is time to forge ahead, remember the lessons learned, and expand the reach of this life saving medicine. In order to operate on a larger scale, changes in the inter-governmental and fiscal systems as well as the transfer of real power, resources, and accountability to local levels is needed. Many community-based projects have paved the way. Yet these discrete projects face the challenge of scaling up efforts into sustainable national programs that build governance and state capacities. As such continued advocacy, education and training are needed.

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APPENDIX A  
RECRUITING MATERIALS



## LETTER SENT TO INTRODUCE PARTICIPANTS TO THE STUDY

My name is Candice Cristy and I am a graduate student under the direction of Professor Gary Grossman in the Global Technology and Development program of Arizona State University.

I am going to explore how to successfully scale-up training and awareness programs surrounding the correct use of misoprostol to treat postpartum hemorrhage (PPH). I will look at community training initiatives and lessons learned from outreach programs already in place with the aim of identifying best practices for scaling up awareness that can translate into pragmatic approaches for future work in Afghanistan and other countries.

I am recruiting individuals to share their experiences and knowledge regarding scaling up community based training initiatives which will take approximately 30 to 45 minutes. I will either be conducting an interview using Skype or providing a written questionnaire. The Skype interview will be recorded so that answers may be accurately recorded. Responses to questions in either format will be kept confidential and your identity will not be published in this report. Only I will have access to your responses which will be used to prepare the findings of this project. Any recordings will be erased upon completion of the project. If you prefer to not have this interview recorded please let me know so I can make other arrangements.

Your participation in this study is voluntary. If you have any questions concerning the research study, please call me at (xxx) xxx-xxxx\*.

\*Note: This number has been removed to protect the privacy of the researcher.

APPENDIX B  
INFORMED CONSENT

INFORMED CONSENT (WRITTEN)

Dear Participant,

Instructions: Please read the following standardized statement before answering any of the interview questions. The interview will take approximately 30-45 minutes to complete. Thank you for your participation and time.

My name is Candice Cristy and I am a graduate student under the direction of Professor Gary Grossman in the Global Technology and Development program of Arizona State University.

I hope you know that several pilot projects on misoprostol use during home delivery to prevent postpartum hemorrhage have been implemented worldwide. I am conducting a study to understand the opinions of those involved in these studies and next steps for scaling up awareness through community based outreach programs. In particular, I will draw from lessons learned from Jhpiego's work in Afghanistan with health care worker training initiatives. Findings from this study will help governments make policy decisions to reduce maternal deaths and advance women's health objectives.

I have collected information from previous studies that indicate that you were part of the study in Afghanistan or have significant knowledge on these matters. Based on experiences and specific knowledge, I would like to ask you a few questions about community based outreach programs targeting dissemination of misoprostol for PPH indications. The questionnaire will take around 30-45 minutes of your time. There is minimal risk associated with participation in this study and participation is completely voluntary. You may at any time skip a question that you wish not to answer. There is no direct benefit or monetary compensation for participation in this project.

The questionnaire is the next document in this packet. Responses to questions will be kept confidential and your identity will not be published in this report. Only I will have access to your responses which will be used to prepare the findings of this project. You may ask questions or for clarification prior to participation by contacting Candice Cristy (1-619-980-9566; candicecristy@yahoo.com) before or after you fill out the questionnaire.

If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Office of Research Integrity and Assurance, at (480) 965-6788.

Return of the questionnaire will be considered your consent to participate.

Sincerely, Candice Cristy

INFORMED CONSENT (VERBAL)

My name is Candice Cristy and I am a graduate student under the direction of Professor Gary Grossman in the Global Technology and Development program of Arizona State University.

I hope you know that several pilot projects on misoprostol use during home delivery to prevent postpartum hemorrhage have been implemented worldwide. I am conducting a study to understand the opinions of those involved in these studies and next steps for scaling up awareness through community based outreach programs. In particular, I will draw from lessons learned from Jhpiego's work in Afghanistan with health care worker training initiatives. Findings from this study will help governments make policy decisions to reduce maternal deaths and advance women's health objectives.

I have collected information from previous studies that indicate that you were part of the study in Afghanistan or have significant knowledge on these matters. Based on experiences and specific knowledge, I would like to ask you a few questions about community based outreach programs targeting dissemination of misoprostol for PPH indications. The Skype interview will take around 30-45 minutes of your time. There is minimal risk associated with participation in this study and participation is completely voluntary. You may at any time skip a question that you wish not to answer. There is no direct benefit or monetary compensation for participation in this project.

The Skype interview will be recorded so that answers may be accurately recorded. Responses to questions will be kept confidential and your identity will not be published in this report. Only I will have access to your responses which will be used to prepare the findings of this project. Any recordings will be erased upon completion of the project. If you prefer to not have this interview recorded please indicate this now.

If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Office of Research Integrity and Assurance, at (480) 965-6788.

APPENDIX C  
QUESTIONNAIRE

### Participant Information

1. Name of project and/or group affiliation: \_\_\_\_\_
2. Number of years involved with misoprostol studies: \_\_\_\_\_
3. Location of fieldwork: \_\_\_\_\_
4. Title within organization: \_\_\_\_\_

### Postpartum Hemorrhage

Postpartum Hemorrhage (PPH) is one of the serious complications women may have after delivery. To prevent this bleeding, programs have been introduced using misoprostol tablets.

5. What materials have your organization produced/published related to misoprostol and PPH indications in the past few years? Please share copies as available.
6. How has misoprostol been introduced within the community of the working area? Do you have any suggestions to improve misoprostol introduction?
7. What was the community's reaction/opinion to misoprostol use?  
For those of you who have worked within multiple countries, has the reaction/opinion varied? Why do you think that is?
8. Thinking about scaling up, what would you change in terms of distribution?
9. How did you obtain the misoprostol drug?
  - a. Was it difficult to maintain necessary supplies?
  - b. How often did you receive additional supplies?
  - c. Do you have any suggestions about the supply of misoprostol?
10. Was cost a factor in obtaining misoprostol?

### Community Based Outreach

Misoprostol distribution to prevent PPH at home births is a new and innovative practice. As such pilot programs will need to be integrated into existing maternal health programs.

11. In your opinion, what are the key determinants of successful community based advocacy and awareness programs?
  - a. What steps were taken to address local values, beliefs and current needs within the community of the working area?
  - b. How simple is the innovation
  - c. Can misoprostol and its distribution be readily modified to fit local conditions?
  - d. How easy is it to observe the success of these programs?
12. Based on your experience, what lessons have you and your organization learned about community based outreach programs? How can these lessons be applied to training programs and the dissemination of misoprostol for PPH indications in the future?

13. What are the main barriers/problems/limitations/pitfalls encountered with misoprostol introduction and distribution and how did you overcome them?
  - a. What specific actions do you think policy makers/health providers/international agencies can take to overcome these barriers going forward?
  - b. Are there other key actors who can participate in the expansion of misoprostol and universal access?
  - c. Do you think the available data on misoprostol is sufficient to reassure policy makers on the efficacy of misoprostol and method of distribution? If not, what additional research is needed?
14. What are the main activities your organization is pursuing to promote misoprostol and PPH awareness over the next 1-2 years?
15. Who are the target audiences for misoprostol and PPH awareness programs?
  - a. At the global level?
  - b. At the regional level?
  - c. At the country level?
16. Currently tablets are supplied by health care workers. If this program were scaled up would this approach be sustainable. If no, why not? What should be done differently?

#### Expansion of outreach programs

The ultimate aim is to expand misoprostol distribution to prevent PPH at home births by scaling up pilot programs and expanding awareness. One important way to do this is to better understand the outcomes and lessons learned from past and ongoing studies.

17. If governments want to scale up use of misoprostol, what challenges/barriers do you foresee? Do you have suggestions for overcoming these challenges?
18. Based on your experience, what recommendations can you offer regarding potential scale-up and replication of training programs?
19. How would you suggest training directives and best practices for misoprostol dissemination, dosage, and usage be integrated into existing health care training programs or safe motherhood structures?
20. If anything, what would you do differently if you were starting a new training program?
21. What are the risks associated with scaling-up these types of programs and misoprostol use?

22. Given competition for scarce resources and competing public health needs how expensive are training programs and how much money is needed to sustain them? Are the people and resources in place for scaling-up awareness efforts?
23. How do training programs adjust to the literacy levels of the community? Were these tactics successful?
24. How do the local norms and cultures related to pregnancy and labor influence training program materials? How would this impact scaling up training initiatives?
25. Does scaling-up or expansion make it more difficult to monitor objectives? Will this make misuse of the program and misoprostol more likely?
26. How can upcoming forums or global events be used as a platform for furthering advocacy and awareness campaigns (agendas) regarding misoprostol use for PPH?
27. What other suggestions/comments do you have regarding the scale up of community based outreach programs that promote misoprostol for PPH?
28. Can you think of any other stakeholders that would be willing to speak to me about this topic? If so, may I ask for their contact information?

**Thank you for your time and participation**



## APPENDIX D

### APPROVAL FROM ETHICAL REVIEW BOARD

**To:** Gary Grossman

Interdisci

**From:** Mark Roosa, Chair

Soc Beh IRB

**Date:** 02/13/2013

**Committee Action:** Exemption Granted

**IRB Action Date:** 02/13/2013

**IRB Protocol #:** 1212008647

**Study Title:** Scaling Up Community Based Distribution and Administration of Misoprostol:  
Afghanistan

The above-referenced protocol is considered exempt after review by the Institutional Review Board pursuant to Federal regulations, 45 CFR Part 46.101(b)(2) . This part of the federal regulations requires that the information be recorded by investigators in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. It is necessary that the information obtained not be such that if disclosed outside the research, it could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation.

You should retain a copy of this letter for your records.